

# **EXHIBIT I**

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>.

# Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

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**1948 – 2009**



Dr. Rodney Appell served as Professor of Urology and Gynecology and Chief, Division of Voiding Dysfunction and Female Urology, at Baylor College of Medicine and held a large private practice in Houston, Texas. He was a highly respected surgeon in female urology and an active member of the American Urological Association (AUA), serving on the Practice Guidelines Committee and the Special Women's Issues in Urology Committee.

At the time of his death, he was Chair of the expert Panel that developed the Stress Urinary Incontinence Clinical Guideline. Directing the Panel members through the painstaking and analytical challenge of systematically reviewing clinical studies so that appropriate practice recommendations could be made was an undertaking at which Dr. Appell excelled. In remembering him, the current guideline Chair, Roger R. Dmochowski, M.D., Professor, Dept of Urologic Surgery, Vanderbilt University, speaking for the Panel, remarked that "Rodney will be missed by us all. His vision of mentorship was the inspiration for a whole generation of residents and fellows. Those of us who knew him will treasure the memory of his unique insight and clinical expertise."

After receiving his medical degree from Jefferson Medical College, Dr. Appell completed his surgical residency at George Washington University Medical Center and residency in urology at Yale University. Since that time and until his death he achieved extensive accomplishments in his field through research, clinical practice, and education activities. Consistently included in the publication *The Best Doctors in America*, Dr. Appell published over 100 full papers or editorials in peer-reviewed journals, authored several book chapters, was invited to participate in more than 200 lectureships and symposia, and delivered over 800 educational talks and presentations both across the United States and around the world. He served on the editorial boards of many publications, including the AUA Journal of Urology. In February 2008, he was awarded the Lifetime Achievement Award by the Society for Urodynamics and Female Urology and was named Continence Care Champion by the National Association for Continence.

Dr. Appell's leadership and expertise will be missed by all who knew him. The Stress Urinary Incontinence Guidelines Panel dedicates this Clinical Guideline to his memory.

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## ***Introduction***

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.<sup>1</sup> A large meta-analysis reported an estimated prevalence for urinary incontinence of 30% in women aged 30 to 60 years, with approximately half of the cases attributed to SUI;<sup>2</sup> another study reported the prevalence of SUI was 5% to 30% in European women.<sup>3</sup> Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year. The first Female Stress Urinary Incontinence Clinical Guidelines Panel reviewed literature available up to January 1994 and published its report in 1997.<sup>4</sup> Since that time, a new body of literature has emerged on primarily novel surgical interventions for the treatment of SUI. For these reasons, the American Urological Association (AUA) has elected to update the initial report on the Surgical Management of Stress Urinary Incontinence. The literature search used in this analysis had a conclusion date of June 2005; it is recognized that this guideline will likely change in response to new information and further developments in the field.

In the 1997 guideline, the index patient was an otherwise healthy female patient with SUI without significant pelvic organ prolapse. It has become apparent since the prior guideline that many women with SUI also have pelvic organ prolapse and that these two issues may be addressed concurrently. Therefore, in constructing this guideline update, the index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and prolapse who elects to have treatment of her

SUI along with surgical correction of prolapse. The current Female Stress Urinary Incontinence Guideline Update Panel (the Panel) was selected by the Panel chair and approved by the Practice Guidelines Committee (PGC) of the AUA. The Panel members are representative of different medical specialties and geographic regions of the U.S. and are from both academic and private institutions.

This report describes an analysis of efficacy and safety outcomes for surgical procedures for use in treatment of SUI and provides a guideline based on review of these data and/or panel consensus. It also offers a discussion about the diagnostic evaluation of the index patient and recommendations for outcomes reporting and future research.

## **Definitions**

Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom – SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies. For the purposes of this guideline, it is assumed that patients in the extracted studies had surgical management of SUI.

Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer<sup>5</sup> or a strong need to pass urine for fear of leakage.<sup>6</sup> Urge urinary incontinence is defined as

involuntary leakage accompanied by or immediately preceded by urgency.<sup>5</sup> Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

### ***Index patient***

The index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse. Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency. Urethral hypermobility was defined by the author; no uniform definition was used.

### ***Methodology***

This guideline included analysis of those relevant factors (perceived risks and outcomes of the interventions, patient preferences and relative priorities of the interventions given limited health care resources) used to choose among alternative treatment interventions.<sup>7</sup> The peer-reviewed medical literature was meta-analyzed to estimate outcomes of treatment modalities, and Panel members themselves served as proxies for patients in considering preferences. The steps taken to develop this guideline, further detailed in Chapter 2, included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval and dissemination. The Panel did not review needle suspensions or anterior colporrhaphy in



developing this guideline update. Since development of the 1997 guideline, very limited new data has been published addressing these procedures, and there is a lack of current use or interest in them as well. Though these operations may still be performed in isolated circumstances by some surgeons, the Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.

### **Problem Definition**

This guideline update was based on the original AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997 using a similar methodology. The analysis was likewise limited to surgical treatments but included new procedures and those considered the most efficacious as determined by the previous analysis. Unlike the 1997 guideline, outcomes of surgical therapies for prolapse were also included.

Surgical efficacy was defined in three parts: 1) the resolution and lack of recurrence of SUI and urgency; 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse; and 3) the incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on patient quality of life. The treatments included in the analysis were retropubic suspensions, slings, injection therapy and artificial sphincters; the analysis excluded those procedures not generally available in the U.S. or not expected to be approved at the time of publication. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.

## **Literature Search and Data Extraction**

A database was generated that included articles retrieved for the previous guideline and those resulting from a series of four MEDLINE® searches beginning in December 2002 and concluding in June 2005. The searches were limited to papers involving human subjects and published in the English language on or after 1990 which included the MeSH term “female.” The MeSH headings used were “urinary incontinence, stress,” “stress incontinence” and “urinary incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance by the panel chairs, of which 1,302 citations entered the extraction process. Panel members extracted data from the articles which were then entered into a Microsoft Access® (Microsoft, Redmond, WA) database. In person and via conference calls, the Panel collectively reviewed the extracted data. A total of 436 articles were suitable for inclusion in the meta-analysis; an additional 155 articles were deemed suitable only for their complications data due to an insufficient follow-up duration for the efficacy outcomes analysis.

## **Evidence Combination**

To generate outcomes tables, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this guideline, the panel used the confidence profile method,<sup>8,9</sup> which provides methods for meta-analyzing data from studies that are not randomized controlled trials (RCTs). Meta-analysis was performed using the Fast\*Pro software to combine individual arms from controlled trials and clinical series where similar patients were similarly treated. Although a number of RCTs were found through the literature search, there were insufficient numbers on any one topic to warrant an independent meta-analysis of RCTs. The results of

certain trials are discussed where relevant. Frequently, published series used in a combined analysis showed very divergent results implying site-to-site variations, variability in patient populations, in the performance of the intervention, the skill of the surgeon or normal statistical variation. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

### **Patient Groups**

While stratifying outcomes based on patient characteristics such as type of incontinence, previous treatment(s), presence of prolapse, prior pregnancy and severity of incontinence would be most instructive, in most cases the outcomes data were not fully or consistently identified by these criteria. Therefore, analysis was limited to two patient groups; one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline) and another in which some or all patients received concomitant treatment for prolapse. Very few published studies included all of the SUI patients receiving concomitant prolapse treatment, therefore, the analysis was based mainly on data from studies that included some patients with prolapse treatment. This did not permit a clear distinction to be made between these groups in the analysis. An attempt to stratify the outcomes of SUI surgical interventions by the presence of prolapse was thwarted by insufficient data since few published studies stratified results in this manner.

### **Efficacy Analysis**

The efficacy outcomes analyzed included two levels of continence: cured/dry and cured/dry/improved; these are reported percentages and credible intervals (Bayesian confidence intervals [CIs]). Allocation to the previously mentioned categories was determined by author definition of continence. For the analysis of postoperative urgency, patients were divided into

three categories: without pre-existing urgency, with pre-existing urgency, and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. Again, the results are reported as the percent of the relevant patient group having each outcome. Abbreviated tables summarizing the cured/dry and resolution or urge incontinence for the time interval of 12-23 months for patients with or without concurrent prolapse treatment are provided with this document (see Tables 1–3); for a complete set of data tables see Appendices A7-A16.

## **Complications**

Complications were analyzed similarly to the efficacy outcomes. However, because of the wide variety of ways authors name and describe complications, the panel attempted to group complications together that represented the same or related outcomes. As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Appendix A-17 shows how the panel grouped outcomes. Certain complication outcomes such as pain and de novo urgency were tabulated as defined by the author, and no further analysis was performed based upon the limitations of data reporting. After grouping the complications for analysis, the grouped complications were then put into general categories for display and discussion. Outcomes tables were developed for each group of complications. Separate tables were again created for patients with and without prolapse treatment. The format of the tables is the same as the efficacy tables. An abbreviated table summarizing retention data for patients with or without concurrent prolapse treatment is provided with this document (see Table 4); for a complete set of data tables see Appendices A7 – A16.

## Guideline Generation and Approvals

After the evidence was combined and outcome tables were produced, the Panel reviewed the results and identified anomalies, updated the outcomes tables based on the problems identified, and based on evidence from the outcome tables and expert opinion, the Panel drafted the treatment guideline. Based on 24 peer reviewer comments, the Panel revised the document. The guideline was submitted for approval to the PGC of the AUA and the Board of Directors for final approval.

As in the previous guideline, the present statements are graded with respect to the degree of flexibility in application. Although the terminology has changed slightly, the current three levels are essentially the same as in the previous guideline. A "standard" has the least flexibility as a treatment policy. A "recommendation" has significantly more flexibility, and an "option" is even more flexible. These terms are defined as follows:

1. **Standard:** A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. **Recommendation:** A guideline statement is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.
3. **Option:** A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

## **Dissemination**

The guideline is published on the web site for the AUA and can be found at

<http://www.auanet.org>. A version of Chapter 1 will be published in the *Journal of Urology*.

## ***Diagnostic Evaluation of the Index Patient***

The purpose of diagnostic evaluation is three-fold: 1) to document and characterize SUI; 2) to assess differential diagnosis and comorbidities; and 3) to prognosticate and aid in the selection of treatment.

### **To confirm the diagnosis and characterize SUI**

Stress urinary incontinence may be characterized by the following:

- demonstration of leakage with increasing abdominal pressure (see below)
- frequency of incontinence episodes (diagnosed by history, questionnaire, bladder diary)
- severity (the volume of urine leakage diagnosed by history, questionnaire, bladder diary, pad test)
- degree of bother (diagnosed by history, bladder diary, questionnaire)
- sphincter function (diagnosed by examination, Valsalva leak point pressure, urethral pressure profile)
- degree of urethral mobility (diagnosed by estimation at time of physical examination, cotton-swab test, or imaging)

On the basis of a focused history and physical examination with a comfortably full bladder, the diagnosis of SUI is fairly straightforward in the index patient. The *sine-qua-non* for a definitive diagnosis is for the examiner to witness involuntary urine loss from the urethral meatus

coincident with increased abdominal pressure (positive stress test) such as those occurring during coughing and straining; a standing position may facilitate the diagnosis. Once the increase in abdominal pressure has subsided, flow through the urethra should subside. Rarely, one may witness urine loss after increases in intra-abdominal pressure. In this scenario, one should suspect that the incontinence is, at least in part, due to an abnormal detrusor contraction (stress-induced detrusor overactivity).

### **To assess differential diagnosis and comorbidities**

The differential diagnosis of stress incontinence includes detrusor overactivity, low bladder compliance, overflow incontinence, stress-induced detrusor overactivity, urethral diverticulum, urinary fistula and ectopic ureter. Overflow incontinence is a clinical diagnosis, whereas detrusor overactivity, low bladder compliance, and stress-induced detrusor overactivity are essentially urodynamic diagnoses while urethral diverticulum and urinary fistula can be sometimes be confirmed on the basis of history and exam but may in some instances require urinary tract imaging or other procedures for confirmation. Various imaging techniques for urethral diverticula may be used. Urinary fistula and ectopic ureter may be diagnosed by examination, cystoscopy and upper and lower urinary tract imaging.

Certain comorbidities relating to coexisting conditions might affect the outcome of treatment and influence surgical technique and the specifics of patient counseling. For example, a patient with mixed and stress incontinence who has a large post-void residual volume and impaired detrusor contractility might be counseled that her urge symptoms are more likely than usual to persist and that urinary retention is more likely. Further, the technique of surgery might be tailored such that a mid urethral, rather than bladder neck, sling is performed and it might be placed a bit looser than otherwise. These comorbidities include:

- urinary urgency and urge incontinence (diagnosed by history, questionnaire, bladder diary);
- anatomic features such as pelvic organ prolapse (diagnosed by history, exam); urethral mobility and other urethral abnormalities such as intrinsic stricture disease (diagnosed by cystoscopy, cotton-swab test, ultrasound);
- the number and location of ureteral orifices e.g. ectopic (diagnosed by cystoscopy); and/or
- the presence of detrusor overactivity, urethral obstruction, low bladder compliance and impaired or absent detrusor contractility (diagnosed by uroflow, postvoid residual volume determination, urodynamics).

### **To aid in prognosis and selection of treatment**

There are few facts and many opinions about predicting the outcome of surgery based on the comorbidities described above, though few would disagree that operations for SUI should be confined to those who actually have demonstrable SUI, including occult SUI demonstrable only after reduction of pelvic organ prolapse. There is no standardized way to reduce a prolapse to unmask stress incontinence, and this patient falls outside the index patient identified by the panel. Nevertheless, an understanding of the specific comorbidities allows for individualized treatment planning, for informed consent and for the surgeon's estimate of a successful outcome and the potential occurrence of complications such as incomplete bladder emptying, persistent or de novo urgency/urge incontinence and recurrent sphincter incontinence. Urodynamic evaluation may be of assistance in elucidating complex presentations of incontinence.



## ***Diagnostic Guidelines for the Index Patient***

Amendments to 1997 Standards, Recommendations and Options are indicated (words that are in italics denote changes from the 1997 guideline document to improve clarity).

**Standard: The evaluation of the index patient should include the following components:**

- ***Focused* history**
- ***Focused* physical examination**
- **Objective demonstration of SUI**
- ***Assessment of postvoid residual urine volume***
- **Urinalysis, and culture if indicated**

[Based on Panel consensus]

**Recommendation: Elements of the history should include the following:**

- **Characterization of incontinence (stress, urge, etc.)**
- **Frequency, bother and severity of incontinence episodes**
- **Impact of symptoms on lifestyle**
- **Patient's expectations of treatment**

[Based on Panel consensus]

**Recommendation: Additional diagnostic studies can be performed to assess the integrity and function of the lower urinary tract.**

- **Pad testing and/or voiding diary**
- **Urodynamics**

- **Cystoscopy**
- **Imaging**

[Based on Panel consensus]

**Recommendation: Indications for further testing include the following:**

- **An inability to make a definitive diagnosis based on symptoms and the initial evaluation**
- **Concomitant overactive bladder symptoms**
- **Prior lower urinary tract surgery, including failed anti-incontinence procedures**
- **Known or suspected neurogenic bladder**
- **Negative stress test**
- **Abnormal urinalysis such as unexplained hematuria or pyuria**
- **Excessive residual urine volume**
- **Grade III or greater pelvic organ prolapse**
- **Any evidence for dysfunctional voiding**

[Based on Panel consensus]

The need for further evaluation of any given patient depends on a number of other factors including the degree of certainty and comfort that the physician has about the diagnosis, the impact that further studies will have on diagnosis, treatment options and treatment risks and likely outcomes as well as the desire and willingness of the patient to undergo further studies.

## ***Therapeutic Options***

### **Nonsurgical Treatment**

Management of SUI includes the option of nonsurgical therapies. The Panel did not review nonsurgical therapies because they are outside the scope of this report.

### **Surgical Treatment**

The outcomes analyzed fell into two general categories: efficacy outcomes and complications.

The results of the analysis are provided under each treatment below. For a more detailed discussion of the outcomes, see Chapter 3. Comparative results of the meta-analysis of efficacy and complications are shown in the tables and graphs in Chapter 3.

## ***Outcomes Analysis***

### **Efficacy**

The primary efficacy outcome was the resolution of stress incontinence as measured two ways—patients who were completely dry (cured/dry) or patients who showed improvement (cured/dry/improved). The cured/dry/improved measure may include patients who were completely dry. Secondary efficacy outcomes dealt with changes in urgency as described in the methodology section above. Data were accepted as reported except when described in terms that conflicted with the definition in the methodology. For example, if a study reported any patients with minimal persistent incontinence as cured, these data were included only in the cured/dry/improved category.

Outcomes were analyzed separately based on whether the continence evaluation was subjective or objective; only results that were clearly based on subjective or objective criteria

were included in their respective analyses. An additional category was created (defined as “any” method of evaluation) to include all studies irrespective of the method of assessment used. For studies reporting both subjective and objective results, the subjective results for the study were included in the “any” category.

Outcomes also were analyzed separately according to the postsurgical interval of the final assessment of continence, with a minimum period of follow-up of 12 months. Three intervals were analyzed: 12 to 23 months, 24 to 47 months and greater than 48 months. If a study reported data at multiple times during one of these intervals, the time point closest to 18 months, 36 months and 60 months were used for the three time ranges, respectively.

## **Complications**

In order to facilitate the analysis of complications for the various SUI surgical procedures and because of the lack of standardized complications nomenclature in the literature the Panel grouped the reported complications into the following classes:

- Urinary retention      • Perioperative genitourinary      • Delayed genitourinary
- Gastrointestinal      • Vascular      • Neurological
- Infectious      • General medical      • Death

Details of these groups are described in Chapter 3. Appendix A-17 lists the specific complications that were included in each of the above classes. Subjective complications (pain, sexual dysfunction, and voiding dysfunction) were also included as a separate category.

Important complications for specific treatments are discussed below under the relevant treatment.

## ***Surgical Treatments Analyzed - Descriptions and Outcomes***

The surgical treatments analyzed fell into four categories: retropubic suspensions, slings, injectable agents and artificial urinary sphincters (AUS). Within each class, modifications of these treatments were analyzed where appropriate. For some categories, only minimal data were available. As noted in the methods section, definitions of cured, dry and improved were those of the authors.

In this section, brief descriptive results are provided for outcomes. The complete results are provided in Chapter 3 and Appendices A7-A16.

### **Retropubic Suspensions**

Although the techniques for performing retropubic suspensions were essentially unchanged since the 1997 Guideline, the Panel elected to determine if there were any new studies since that analysis that would result in significantly different outcomes. Data from three categories of retropubic suspensions were analyzed: 1) open suspensions regardless of type (including Burch suspensions); 2) open Burch suspensions alone; and 3) laparoscopic suspensions.

The Panel's meta-analysis estimated cured/dry rates at 12 to 23 months based on 1,085 patients for open suspensions with no concomitant prolapse treatment to be 82% (CI: 74%-87%) while cured/dry rates for laparoscopic suspensions were 69% (368 patients; CI: 52%-84%) (Table 1). At 24 to 47 months, the cured/dry rates were similar among all procedures, ranging from 74% to 76%. At 48 months or longer, cured/dry rates for all open procedures were 73%. No data were available for laparoscopic procedures. These rates are similar to those reported for retropubic suspensions in the previous Guideline, in which estimated cured/dry rates were 84% at all time points.<sup>4</sup>

The meta-analysis estimate of postoperative urge incontinence was 14% from data from 186 patients (CI: 6%-25%) with pre-existing urge incontinence when treated with open retropubic suspensions, while de novo urge incontinence and “unspecified” urge incontinence was estimated in 8% (713 patients; CI: 5%-12%) and 41% of patients (305 patients; CI: 30%-54%), respectively (Table 3). Of patients undergoing laparoscopic retropubic suspensions, the meta-analytic results indicate that an estimated 5% of patients (CI: 1%-14%) will experience de novo urge incontinence and approximately 6% (CI: 1%-14%) will have “unspecified” urge incontinence. There were few data available for laparoscopic retropubic suspensions or for longer term outcomes of open retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Based on 1,154 patients in 18 studies, retention could occur in 3% to 4% of patients (Table 4). The most common complications and estimated rates of occurrence for open retropubic suspensions determined in the meta-analysis (see Chapter 3) were febrile complications (8%), urinary tract infection (13%), bladder injury (4%) and voiding dysfunction (9%). Laparoscopic suspensions appeared to have a lower overall risk of febrile complications (0% reported) and urinary tract infection (2%), although these estimates were based on limited data. Ureteral injury was estimated to occur in 4-11% of patients receiving laparoscopic retropubic suspensions (see later discussion in Chapter 3), but only 1% of patients receiving open suspensions. Again, these estimates were based on a very small number of patients.

For patients with concomitant prolapse treatment, the estimated cured/dry rates for open retropubic suspensions, Burch suspensions and laparoscopic suspensions were all 88% at 12 to 23 months and 83% to 85% at 24 to 47 months (Table 2). The cured/dry rate was estimated to be 67% (1,072 patients; CI: 56%-76%) for all open retropubic suspensions at 48 months or longer, and data were insufficient for an approximation of efficacy for laparoscopic therapy at 48 months

or longer. The postoperative urge incontinence rate was based on 143 patients with pre-existing urge incontinence who were treated with open retropubic suspensions with concurrent prolapse repair; the rate of occurrence was approximately 22% (CI: 4%-56%). Further, the analysis estimates 14% of patients (457 patients; CI: 8%-21%) may experience de novo urge incontinence and 13% of patients (256 patients; CI: 7%-22%) may report “unspecified” urge incontinence (Table 3). By comparison, the results estimate that 11% of patients treated with laparoscopic suspensions will have de novo urge incontinence (344 patients; CI: 6%-17%); data were unavailable or insufficient for the other urge incontinent outcomes with laparoscopic retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Retention was estimated in 1% to 2% of patients (Table 4).

## **Slings**

### **Autologous Fascial Slings**

Efficacy data were available for a variety of types of autologous fascial slings, including suprapubic slings with bone anchors, autologous vaginal wall slings with or without bone anchors and the general category of autologous fascial slings without bone anchors (detailed outcomes for the different types of autologous fascial slings are provided in Chapter 3).

Most of the available studies described patients treated with autologous slings without bone anchors. For patients without concurrent prolapse treatment, the estimated cured/dry rates ranged between 90% at 12 to 23 months and 82% at 48 months or longer (Table 1). The Panel’s meta-analysis estimated rates of postsurgical urge incontinence were 33% in patients with pre-existing urge incontinence and de novo urge incontinence in 9% of patients without pre-existing urge incontinence (Table 3). The estimated rate of retention was 8% (Table 4). Complications estimates for autologous fascial slings without bone anchors were generally infrequent and

included urinary tract infection (11%), bladder injury (4%) and wound complications (8%). There were also a few studies published between 2001 and 2003 reporting data on a small number of patients who received autologous fascial vaginal wall slings with or without bone anchors. Complete data are provided in Chapter 3.

For patients treated with autologous slings without bone anchors and a concurrent prolapse treatment, cured/dry rates ranged from 85% to 92%, although these estimates were based on a very small number of patients (Table 2). Based on the results of the meta-analysis, approximately 10% of patients could experience de novo urge incontinence, and an estimated 5% of patients will be subject to retention (Table 3).

### **Cadaveric Slings**

Cadaveric slings came into wide use following a report by Handa et al.,<sup>10</sup> and other authors have since reported favorable results using this procedure.<sup>11, 12</sup> However, the long-term durability of these procedures has been questioned,<sup>13, 14</sup> with reports of graft failure<sup>15, 16</sup> and declining success rates over time<sup>17, 18</sup> (for a more complete discussion on the use of cadaveric slings, see Chapter 3). The use of these materials has dramatically declined over time as a result of these concerns, thus severely limiting data available for analysis.

Based on the limited data available for analysis, the estimated cured/dry rate for patients undergoing cadaveric slings without bone anchors and no concomitant prolapse treatment was 74% at 12 to 23 months and 80% at 24 to 47 months (Table 1). There were no data for longer term efficacy (48 months or longer) for cadaveric slings, and few studies reported data on retention, urge incontinence or complications.

For patients with concomitant prolapse treatment, the Panel's meta-analysis estimates of cure/dry rates were 82% (234 patients CI: 77%-86%) at 12 to 23 months using a cadaveric sling



with bone anchors, whereas the rate was 58% based on patients from three studies totaling 133 patients (CI: 36%-78%) where bone anchors were not utilized (Table 2). Despite the fact that these confidence intervals barely overlap, the consensus of the Panel is that these represent statistical aberrations inherent in evidence combination and are likely not representative of a true difference in outcomes. There were no data for bone-anchored slings beyond two years. At 24 to 47 months, for patients undergoing a cadaveric sling procedure without bone anchors in addition to prolapse treatment, the cured/dry rate was 64%, and at > 48 months based on 13 patients, only an estimated 31% receiving a cadaveric sling without bone anchor will be cured/dry.

Little is known about the graft-host relationship and possible mechanisms of graft degradation for cadaveric materials. In addition, processing and storage of these materials is variable, which could account for the disparity of results as reflected by the wide CIs in our analysis. There were insufficient data to assess the long-term efficacy of these procedures, with very few studies reporting results at 48 months or longer. Furthermore, the risks of disease transmission with these materials remain unknown. Traces of genetic material have been isolated from commercially available cadaveric sling materials<sup>19</sup> although there have been no reports of disease transmission related to cadaveric grafts in the urologic literature.

There were few complications reported in the literature for procedures using cadaveric sling materials. Vaginal extrusion was reported in one study,<sup>20</sup> but erosion of cadaveric materials into the urinary tract was not identified in this meta-analysis. Other reported complications were similar to other procedures for the surgical correction of SUI. When these materials have been used with concomitant prolapse repair, complications such as infection and graft extrusion have been reported.<sup>21</sup>

## **Synthetic Slings**

Efficacy data were available for synthetic slings placed at the bladder neck and synthetic slings placed at the midurethra. Outcomes are discussed separately for each of these procedures.

### **Synthetic Slings at the Bladder Neck**

Efficacy data were available for synthetic slings at the bladder neck with or without bone anchors; most of the data came from studies involving synthetic slings without bone anchors. With this procedure, the estimated cured/dry rate based on 349 patients in nine studies without prolapse treatment was 73% (CI: 64%-80%) at 24 to 47 months; longer term data were not available (Table 1). De novo urgency was approximated at 12% of patients (132 patients; CI: 6%-20%) at 12 to 23 months; there were limited data on other urge incontinence outcomes (Table 3). The retention rate was an estimated 9% (360 patients; CI: 5%-15%) (Table 4). The most common complications occurring with synthetic slings at the bladder neck without bone anchors (provided in Chapter 3) were urinary tract infection (10%) and erosion/extrusion (5% for urethral/bladder, 8% for vaginal and 17% for unknown). However, because only studies that report a given complication were included in the analysis and many of these studies were small case series, these percentages may represent an overestimation of the risk of these complications. Despite these limitations, these data suggest an increased probability of urinary tract erosion following synthetic slings placed at the bladder neck.

For those treated with synthetic slings at the bladder neck with concurrent prolapse treatment, the meta-analysis estimated cured/dry rates of 73% to 75% at 24 months and longer (Table 2). Estimates of postoperative urge incontinence based on 119 patients with pre-existing urge incontinence in three studies was 29% (CI: 16%-46%), and estimates suggested that only

15% of patients (150 patients; CI: 5%-31%) will experience de novo urge incontinence (Table 3). The estimated retention rate was 10% (422 patients; CI: 5%-18%) (Table 4).

### **Synthetic Slings at the Midurethra**

Since the publication of the 1997 guideline, there has been a proliferation of new modifications to the pubovaginal sling that have largely replaced the retropubic suspension and the autologous sling as the primary procedures for SUI. In these procedures the synthetic sling is placed at the midurethra as opposed to the bladder neck. These procedures are performed using one of two techniques –transvaginal/retropubic or transobturator. In the retropubic technique, trocars or long needles are passed at the midurethra through the retropubic space from the vagina to the abdomen or from the abdomen to the vagina. In the transobturator technique, the slings are passed with a curved trocar from the vagina behind the ischium (inside-out) or from the ischium to the vagina (outside-in). At the time of this analysis, data on the transobturator technique was limited, with insufficient numbers of patients having long-term follow-up to reach any conclusions regarding efficacy (see final section of this document for further discussion of these procedures).

For the transvaginal/retropubic technique, the Panel's meta-analysis estimated cured/dry rates in patients without prolapse treatment ranging from 81% to 84% at all time points (Table 1), which is comparable to the medium-term results for the Burch suspensions and autologous fascial slings. De novo urge incontinence was projected in 6% of patients (323 patients; CI: 3%-10%) (Table 3) while retention estimates were 3% of patients (2119 patients; CI: 2%-4%) (Table 4); insufficient data were available for an estimate of resolution of pre-existing urgency, with only 1 group of 25 patients providing data. Complication rates (see Chapter 3) included bladder injury as defined by the study authors (6%), urinary tract infection (11%) and extrusions

(7% for vaginal extrusions and 1% for unknown). Wound complications were also reported in the literature. Thirteen case reports identified the complications of urethral or bladder erosion of mesh into the urinary tract which occurred in over half of a cohort of 33 patients. Unfortunately, the probability of urinary tract erosion was unable to be calculated precisely from the database as all of these were reports of individual cases or small case series which would result in an overestimation of the risk of these complications. Similar efficacy results were found for those treated with midurethral synthetic slings with concurrent prolapse treatment.

### **Mesh in pelvic floor surgery\*\*:**

Recently, the U.S. Food and Drug Administration (FDA) released a warning position statement concerning the use of mesh materials in stress incontinence surgery and pelvic organ prolapse surgery. They noted over 1,000 reported complications of vaginal and urinary erosion as well as bowel and vascular injuries (<http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>). This data has been extracted from the FDA Manufacturer and User Facility Device Experience Database (MAUDE) database, which promotes voluntary reporting of complications. The Panel has reviewed this statement and the results of this meta-analysis. Based on this review, the Panel has reached the following conclusions:

- 1) In this meta-analysis, the midurethral slings had an efficacy comparable to autologous slings in the surgical treatment of SUI.
- 2) Several “versions” of the midurethral sling procedures do not have similar long-term efficacy data.

**\*\*The FDA issued an updated warning in July 2011 regarding the use of vaginal mesh. Please read the alert on the cover of this guideline.**

- 3) There are complications that may occur that are unique to specific mesh materials; however, these complications appear to be rare. Intraoperative use of cystoscopy can be performed to minimize the risk of urinary tract injury or erosion.
- 4) The midurethral sling is an alternative in the management of SUI. The incidence and implications of these complications along with the more rapid recovery and more efficient return to normal voiding after surgery should be discussed with patients before surgery.

### **Injectable Agents**

Injectable agents may provide immediate relief for some patients and are an option for patients who do not wish to undergo more invasive surgery and who understand that both efficacy and duration are inferior to surgery. Other possible indications for the use of injectable agents include patients who are elderly, those who are at high anesthetic risk or those willing to accept an improvement in their incontinence without necessarily achieving dryness.

For this analysis, injectable agents were subdivided into collagen (bovine glutaraldehyde cross-linked) and other nondegradable synthetic agents. The literature reviewed for this guideline offered minimal new data, with sufficient data available for an analysis of only collagen. The anticipated efficacy for patients treated with collagen without concomitant prolapse treatment declined over time, from 48% at 12 to 23 months to 32% at 24 to 47 months (Table 1). The estimated rates of de novo and unspecified urge incontinence as well as the rates of complications were low.

Very limited information is available for the other injectable agents with the exception of the multicenter trials that won approval for these agents by the U.S. FDA. These include carbon-coated zirconium beads in beta-glucan gel<sup>22</sup> and calcium hydroxylapatite.<sup>23</sup> Data regarding newer agents under FDA review or not yet in the literature were not included. There were limited data with which to assess the long-term safety and efficacy of injectable agents. These agents are an option for women who require or prefer a minimally invasive procedure under local anesthesia.

### **Artificial Urinary Sphincters**

In the U.S., use of the AUS is generally restricted to children with nonfunctioning urethras (i.e., those with spina bifida), in adults with nonfunctioning urethras secondary to trauma to the nerves of the pelvis such as following automobile accidents or in male adults with postprostatectomy incontinence. Data on use of the AUS in the index patient are limited. It is occasionally used in a patient with severe intrinsic sphincteric deficiency who has failed other surgical procedures, or patients with significant SUI and poor bladder contractility such as those with diabetes or back injury. Although limited, available data on the AUS in over a decade of use demonstrate that it can be a valuable therapy with a high degree of effectiveness. Erosion, infection and device malfunction are potential complications. Based on the only recent study on complications, an anticipated erosion/extrusion rate was computed to be 28%.<sup>24</sup> With respect to the index patient, the AUS might be useful in the Valsalva-voiding woman who must abdominally strain to empty the bladder. When the cuff is opened for voiding, the AUS is likely nonobstructive to the bladder in contrast to slings where straining may cause obstruction to the flow of urine. The Panel feels that the role of the AUS is limited.

## ***Treatment Guidelines for the Index Patient***

The Panel updated existing guideline statements and developed new statements. Amendments to 1997 Standards, Recommendations and Options are indicated (words that are in italics denote changes from the 1997 guideline document to improve clarity).

**Standard: The patient should be counseled regarding the surgical and nonsurgical options including both benefits and risks. Choice of the procedure should be made as a collaborative effort between the surgeon and patient and should consider both patient preferences and the surgeon's experience and judgment.**

[Based on Panel consensus]

**Standard: Patients with urge incontinence without stress incontinence should not be offered a surgical procedure for stress incontinence.** The index patient has stress urinary incontinence with or without prolapse. The use of a prophylactic anti-incontinence procedure in the patient with occult incontinence with high grade prolapse is not the guideline index patient and the panel does not have an opinion about prophylactic incontinence surgery.

[Based on Panel consensus]

**Recommendation: Synthetic sling surgery is contraindicated in stress incontinent patients with a concurrent urethrovaginal fistula, urethral erosion, intraoperative urethral injury and/or urethral diverticulum.**

[Based on Panel consensus]

Although there is no peer-reviewed literature that specifically evaluates these uncommon conditions, the Panel believes that using synthetic material in these circumstances may place the patient at higher risk for subsequent urethral erosion, vaginal extrusion, urethrovaginal fistula and foreign body granuloma formation. In such patients, the Panel believes that autologous fascial and alternative biologic slings are an option in the treatment of concomitant stress incontinence. The decision to use these materials should be based on the judgment of the surgeon and made in the best interests of the patient.

**Standard: Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.**

[Based on Panel consensus]

For detection of potential intraoperative complications, the bladder and urethra should be inspected either with a rigid or flexible cystoscope prior to the conclusion of the procedure. A short beak rigid cystoscope or flexible fiberoptic cystoscope provides optimal visualization of the female urethra.

**Option: The five major types of procedures (injectables, laparoscopic suspensions, midurethral slings, pubovaginal slings and retropubic suspensions), although not equivalent, may be considered for the index patient.**

[Based on Panel consensus]

Newer techniques and materials for the surgical treatment of stress incontinence such as midurethral synthetic slings have been developed. For the index patient, the Panel believes that these techniques, materials and accompanying physician expertise and



experience offer a number of advantages that include shorter operative time, shorter recovery time and less short-term morbidity; however, urethral erosion and vaginal extrusion of the synthetic material may occur, which can be very difficult to treat. In addition, perforation of bowel and blood vessels, which pose a life-threatening risk, may result from this procedure. Longer term follow-up is needed before any definitive statements regarding the long-term efficacy and life-long risk of erosion with these procedures can be made.

**Option: The artificial urinary sphincter may be indicated in certain circumstances.**

[Based on evidence and Panel opinion]

The Panel considers the use of the AUS in the index patient as an option, with a role limited to patients not amenable to treatment with other procedures.

**Option: Stress incontinence procedures may be considered for patients with mixed incontinence with a significant stress incontinence component.**

[Based on review of the data and Panel consensus]

Ample support exists for the role of surgery in mixed incontinence<sup>25</sup> The meta-analysis estimate of postoperative urge incontinence was 14% from data from 186 patients (CI: 6% - 25%) with pre-existing urge incontinence when treated with open retropubic suspensions while others have reported disparate outcomes.<sup>26</sup>

**Recommendation: Surgical procedures for SUI and prolapse may be safely performed concomitantly in appropriately selected women. Tensioning of any sling should not be performed until prolapse surgery is completed.**

[Based on Panel consensus]

## ***Recommendations for Future Research and Reporting***

### **Recommendations to Editors and Reviewers**

Although more than a decade has passed since the recommendations for improving the quality of data from clinical trials and studies were proposed by Leach et al.,<sup>4</sup> very little progress has been made by editors and reviewers in instituting these recommendations.<sup>27</sup> Furthermore, the FDA has not altered the approval process as discussed below. Thus, again, the Panel members were extremely disappointed in data available for meta-analysis. In addition to the specific data outlined by Leach et al.<sup>4</sup> in the original Panel report, editors and their reviewers should require:

- Defined outcome measures obtained preoperatively and followed postoperatively
  - validated questionnaires
  - bladder diary
  - pad test
  - exam with full bladder
- A minimum follow-up of at least 12 months of all surgically treated patients for reporting of efficacy data
- A grading of the degree of prolapse (anterior, posterior, apical) as determined by preoperative pelvic examination recorded on all patients

For adverse event data, complications should be categorized as occurring intraoperatively or postoperatively. It is essential to report the following adverse event data:

- Overactive bladder symptoms, which should include persistent overactivity (already present preoperatively) or de novo overactivity (occurring as a complication of the surgery)
- Persistent or de novo other lower urinary tract symptoms
- Urinary retention of greater than four weeks and/or requiring intervention
- Infection (reported as wound infection, vaginal infection, symptomatic urinary tract infection, pelvic abscess, etc.)
- Fever (sepsis)
- Postoperative pain, bleeding, thromboembolus formation (lower extremity, pulmonary or other)
- Lower urinary tract or vaginal injury or erosion
- Refractory pain
- Other serious complications, including vascular or bowel injury, death

The profession at large and the individual physician should insure the safety and efficacy of any new device or sling. If safety and efficacy has not been shown with reasonable certainty, the new treatment should only be performed as part of clinical research studies and/or with informed consent recognizing that safety and/or efficacy has not been demonstrated.

## **Transobturator Tape Procedures**

As previously discussed, modifications to the pubovaginal sling since the 1997 guideline include development of two minimally invasive procedures for the surgical treatment of SUI: the tension-free vaginal tape procedure introduced in 1996,<sup>28</sup> and the transobturator technique, introduced in 2001.<sup>29-31</sup>

In the development of this guideline, the Panel established June 2005 as a cut-off date for literature review. At that time, the transobturator was a novel procedure with limited information available in the published literature, precluding inclusion of the procedure in the data analyses. Since that deadline, numerous articles have been published in the peer-reviewed literature regarding the transobturator procedure. The Panel is very aware of the importance of the transobturator procedure in the current practice of urology and urogynecology.

## **Conflict of Interest Disclosures**

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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**Acknowledgments and Disclaimers: Guidelines for the Management of Female Stress Urinary Incontinence: 2009 Update**

This document was written by the Female Stress Urinary Incontinence Update Panel of the American Urological Association Education and Research, Inc., which was created in 2002. The PGC of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the committee included urologists and gynecologists with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the diagnosis and surgical treatment of female SUI. This document was submitted for peer review to 76 urologists and other healthcare professionals. After the final revisions were made, based upon the peer review process, the document was submitted to and approved by the PGC and the Board of Directors of the AUA. Funding of the committee was provided by the AUA. Committee members received no remuneration for their work. Each member of the committee provided a conflict of interest disclosure to the AUA.

This report is intended to provide medical practitioners with a consensus of principles and strategies for the surgical treatment of female stress urinary incontinence. The report is based on current professional literature, clinical experience and expert opinion. It does not establish a fixed set of rules or define the legal standard of care, and it does not preempt physician judgment in individual cases.

| Table 1. Cured/dry analysis – No concurrent prolapse treatment* |              |                              |            |  |              |                               |            |  |            |                               |
|---|--------------|------------------------------|------------|--|--------------|-------------------------------|------------|--|------------|-------------------------------|
|   | 12-23 months |                              |            |  | 24-47 months |                               |            |  | ≥48 months |                               |
|   | G/P          | Median%<br>(CI 2.5% - 97.5%) |            |  | G/P          | Median %<br>(CI 2.5% - 97.5%) |            |  | G/P        | Median %<br>(CI 2.5% - 97.5%) |
| Suspensions   |              |                              |            |  |              |                               |            |  |            |                               |
| All Open Retropubic   | 15/1085      | 82%                          | (74 - 87)% |  | 13/803       | 76%                           | (68 - 82)% |  | 17/1259    | 73% (64 - 77)%                |
| Burch   | 14/1070      | 81%                          | (73 - 87)% |  | 12/775       | 76%                           | (68 - 83)% |  | 13/1065    | 73% (65 - 80)%                |
| Laparoscopic  | 9/368        | 69%                          | (52 - 84)% |  | 4/172        | 74%                           | (61 - 85)% |  |            |                               |
| Slings  |              |                              |            |  |              |                               |            |  |            |                               |
| Autologous fascial  |              |                              |            |  |              |                               |            |  |            |                               |
| without bone anchors  | 4/342        | 90%                          | (76 - 98)% |  | 6/232        | 81%                           | (72 - 88)% |  | 4/368      | 82% (67 - 93)%                |
| vaginal wall slings w/without bone anchors                      | 1/39         | 79%                          | (65 - 90)% |  |              |                               |            |  | 1/29       | 96% (85 - 100)%               |
| vaginal wall slings with bone anchors                           |              |                              |            |  | 1/58         | 79%                           | (68 - 88)% |  |            |                               |
| Cadaveric without bone anchors                                  | 1/104        | 74%                          | (65 - 82)% |  | 2/71         | 80%                           | (43 - 98)% |  |            |                               |
| Synthetic at bladder neck                                       |              |                              |            |  |              |                               |            |  |            |                               |
| with bone anchors   | 2/34         | 88%                          | (71 - 97)% |  |              |                               |            |  | 1/27       | 92% (78 - 98)%                |
| without bone anchors  |              |                              |            |  | 9/349        | 73%                           | (64 - 80)% |  |            |                               |
| Synthetic at midurethra   | 14/1215      | 84%                          | (78 - 89)% |  | 7/483        | 81%                           | (72 - 88)% |  | 3/199      | 84% (77 - 89)%                |
| Injectables   |              |                              |            |  |              |                               |            |  |            |                               |
| Collagen  | 7/340        | 48%                          | (41 - 55)% |  | 4/210        | 32%                           | (24 - 42)% |  | 1/40       | 30% (18 - 45)%                |

G=number of groups/arms in analysis; P=number of patients in analysis

\*By any evaluation method, including subjective and objective

| Table 2. Cured/dry analysis: ANY patient in the group/arm receiving concurrent prolapse treatment* |              |                              |             |  |              |                               |            |  |            |                               |
|--|--------------|------------------------------|-------------|--|--------------|-------------------------------|------------|--|------------|-------------------------------|
|  | 12-23 months |                              |             |  | 24-47 months |                               |            |  | ≥48 months |                               |
|  | G/P          | Median%<br>(CI 2.5% - 97.5%) |             |  | G/P          | Median %<br>(CI 2.5% - 97.5%) |            |  | G/P        | Median %<br>(CI 2.5% - 97.5%) |
| Suspensions  |              |                              |             |  |              |                               |            |  |            |                               |
| All Open Retropubic  | 9/517        | 88%                          | (83 - 92)%  |  | 9/403        | 83%                           | (75 - 90)% |  | 13/1072    | 67% (56 - 76)%                |
| Burch  | 9/517        | 88%                          | (83 - 92)%  |  | 7/333        | 85%                           | (75 - 93)% |  | 12/954     | 65% (53 - 74)%                |
| Laparoscopic   | 12/564       | 88%                          | (85 - 91)%  |  | 7/359        | 83%                           | (73 - 91)% |  | 1/34       | 88% (74 - 96)%                |
| Slings   |              |                              |             |  |              |                               |            |  |            |                               |
| Autologous fascial   |              |                              |             |  |              |                               |            |  |            |                               |
| without bone anchors   | 3/78         | 92%                          | (82 - 97)%  |  | 1/80         | 85%                           | (76 - 92)% |  |            |                               |
| vaginal wall slings w/without bone anchors   | 1/20         | 70%                          | (48 - 86)%  |  | 2/60         | 89%                           | (64 - 99)% |  | 1/82       | 95% (89 - 98)%                |
| vaginal wall slings with bone anchors, suprapubic  | 1/19         | 99%                          | (88 - 100)% |  | 1/9          | 87%                           | (59 - 99)% |  |            |                               |
| Cadaveric  |              |                              |             |  |              |                               |            |  |            |                               |
| with bone anchors -transvaginal  | 1/234        | 82%                          | (77 - 86)%  |  |              |                               |            |  |            |                               |
| without bone anchors   | 3/133        | 58%                          | (36 - 78)%  |  | 2/92         | 64%                           | (21 - 95)% |  | 1/13       | 31% (11 - 58)%                |
| Homologous dermis without bone anchors   |              |                              |             |  | 1/19         | 89%                           | (70 - 98)% |  |            |                               |
| Synthetic at bladder neck  |              |                              |             |  |              |                               |            |  |            |                               |
| with bone anchors-suprapubic   |              |                              |             |  |              |                               |            |  | 1/49       | 85% (74 - 93)%                |
| with bone anchors- transvaginal  |              |                              |             |  | 1/32         | 81%                           | (65 - 92)% |  |            |                               |
| without bone anchors   | 1/20         | 94%                          | (79 - 99)%  |  | 3/184        | 75%                           | (56 - 90)% |  | 3/182      | 73% (62 - 82)%                |
| Synthetic at midurethra  | 14/1089      | 85%                          | (80 – 89)%  |  | 11/881       | 87%                           | (81 - 91)% |  | 2/101      | 76% (64 - 85)%                |
| Other Sling  | 1/126        | 92%                          | (86 - 96)%  |  |              |                               |            |  |            |                               |

G=number of groups/arms in analysis; P=number of patients in analysis

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.



| Table 3. Urge incontinence outcomes at 12-23 months |                         |                              |            |  |              |                               |             |  |             |                               |
|---|-------------------------|------------------------------|------------|--|--------------|-------------------------------|-------------|--|-------------|-------------------------------|
|   | No Prolapse Treatment   |                              |            |  |              |                               |             |  |             |                               |
|   | De Novo                 |                              |            |  | Pre-Existing |                               |             |  | Unspecified |                               |
|   | G/P                     | Median%<br>(CI 2.5% - 97.5%) |            |  | G/P          | Median %<br>(CI 2.5% - 97.5%) |             |  | G/P         | Median %<br>(CI 2.5% - 97.5%) |
| Suspensions   |                         |                              |            |  |              |                               |             |  |             |                               |
| All Open Retropubic                                 | 10/713                  | 8%                           | (5 - 12)%  |  | 5/186        | 14%                           | (6 - 25)%   |  | 4/305       | 41%   (30 - 54)%              |
| Burch   | 9/695                   | 8%                           | (5 - 11)%  |  | 3/108        | 17%                           | (4 - 40)%   |  | 4/305       | 41%   (30 - 54)%              |
| Laparoscopic  | 2/112                   | 5%                           | (1 - 14)%  |  |              |                               |             |  | 2/100       | 6%     (1 - 14)%              |
| Slings  |                         |                              |            |  |              |                               |             |  |             |                               |
| Autologous fascial                                  |                         |                              |            |  |              |                               |             |  |             |                               |
| without bone anchors                                | 4/329                   | 9%                           | (6 - 13)%  |  | 4/358        | 33%                           | (28 - 40)%  |  |             |                               |
| vaginal wall slings w/without bone anchors          |                         |                              |            |  | 1/13         | 9%                            | (1 - 31)%   |  |             |                               |
| vaginal wall slings with bone anchors               |                         |                              |            |  |              |                               |             |  |             |                               |
| Cadaveric without bone anchors                      | 1/25                    | 28%                          | (13 - 47)% |  | 1/38         | 21%                           | (10 - 36)%  |  |             |                               |
| Synthetic at bladder neck with bone anchors         |                         |                              |            |  | 1/6          | 96%                           | (67 - 100)% |  |             |                               |
| Synthetic at bladder neck without bone anchors      | 4/132                   | 12%                          | (6 - 20)%  |  | 1/24         | 17%                           | (6 - 35)%   |  |             |                               |
| Synthetic at midurethra                             | 7/323                   | 6%                           | (3 - 10)%  |  | 1/25         | 44%                           | (26 - 63)%  |  | 2/532       | 22%   (3 - 58)%               |
| Other Sling   |                         |                              |            |  |              |                               |             |  |             |                               |
| Injectables   |                         |                              |            |  |              |                               |             |  |             |                               |
| Collagen  | 1/337                   | 13%                          | (10 - 17)% |  |              |                               |             |  | 1/50        | 8%     (3 – 18)%              |
|   | Any Prolapse Treatment* |                              |            |  |              |                               |             |  |             |                               |
| Suspensions   |                         |                              |            |  |              |                               |             |  |             |                               |
| All Open Retropubic                                 | 10/457                  | 14%                          | (8 - 21)%  |  | 2/143        | 22%                           | (4 - 56)%   |  | 2/256       | 13%   (7 - 22)%               |
| Burch   | 9/417                   | 14%                          | (8 - 22)%  |  | 1/25         | 48%                           | (30 - 67)%  |  | 2/256       | 13%   (7 - 22)%               |
| Laparoscopic  | 5/344                   | 11%                          | (6 - 17)%  |  |              |                               |             |  | 1/32        | 4%     (0 - 14)%              |
| Slings  |                         |                              |            |  |              |                               |             |  |             |                               |
| Autologous fascial                                  |                         |                              |            |  |              |                               |             |  |             |                               |

|  |        |     |           |  |       |     |            |       |              |
|--|--------|-----|-----------|--|-------|-----|------------|-------|--------------|
| without bone anchors                             | 2/97   | 10% | (4 - 19)% |  |       |     |            |       |              |
| vaginal wall slings w/without bone anchors       | 3/65   | 13% | (2 - 36)% |  | 2/15  | 47% | (21 - 75)% |       |              |
| vaginal wall slings with bone anchors suprapubic | 1/9    | 13% | (1 - 41)% |  |       |     |            |       |              |
| Cadaveric with bone anchors - transvaginal       | 1/238  | 6%  | (3 - 9)%  |  |       |     |            |       |              |
| Homologous tissue (dermis) without bone anchors  | 1/5    | 22% | (2 - 63)% |  |       |     |            |       |              |
| Synthetic at bladder neck without bone anchors   | 4/150  | 15% | (5 - 31)% |  | 3/119 | 29% | (16 - 46)% |       |              |
| Synthetic at midurethra                          | 11/805 | 11% | (7 - 16)% |  | 5/107 | 52% | (38 - 66)% | 2/174 | 9% (1 - 38)% |

G=number of groups/arms in analysis; P=number of patients in analysis

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

| <b>Table 4. Retention*</b>                 |                              |                                     |           |                                 |                                       |
|--|------------------------------|-------------------------------------|-----------|---------------------------------|---------------------------------------|
|  | <b>No prolapse treatment</b> |                                     |           | <b>Any prolapse treatment**</b> |                                       |
|  | <b>G/P</b>                   | <b>Median%<br/>(CI 2.5%- 97.5%)</b> |           | <b>G/P</b>                      | <b>Median %<br/>(CI 2.5% - 97.5%)</b> |
| <b>Suspensions</b>                         |                              |                                     |           |                                 |                                       |
| All Open Retropubic                        | 8/619                        | 4%                                  | (1 - 8)%  | 13/851                          | 1% (1 - 3)%                           |
| Burch                                      | 5/347                        | 3%                                  | (1 - 7)%  | 10/710                          | 1% (1 - 3)%                           |
| Laparoscopic                               | 5/188                        | 4%                                  | (1 - 8)%  | 11/482                          | 2% (1 - 4)%                           |
| <b>Slings</b>                              |                              |                                     |           |                                 |                                       |
| Autologous fascial                         |                              |                                     |           |                                 |                                       |
| without bone anchors                       | 8/480                        | 8%                                  | (4 - 15)% | 3/301                           | 5% (2 - 11)%                          |
| vaginal wall slings w/without bone anchors | 2/68                         | 2%                                  | (0 - 8)%  | 3/142                           | 5% (1 - 17)%                          |
| Suprapubic                                 |                              |                                     |           | 1/25                            | 1% (0 - 9)%                           |
| Cadaveric without bone anchors             |                              |                                     |           | 1/26                            | 1% (0 - 10)%                          |
| Synthetic at bladder neck                  |                              |                                     |           |                                 |                                       |
| with bone anchors - suprapubic             |                              |                                     |           | 1/49                            | 4% (1 - 12)%                          |
| with bone anchors - transvaginal           |                              |                                     |           | 2/99                            | 1% (0 - 6)%                           |
| without bone anchors                       | 4/360                        | 9%                                  | (5 - 15)% | 7/422                           | 10% (5 - 18)%                         |
| Synthetic at midurethra                    | 17/2119                      | 3%                                  | (2 - 4)%  | 11/1107                         | 3% (2 - 5)%                           |
| <b>Injectables</b>                         |                              |                                     |           |                                 |                                       |
| Collagen                                   | 2/104                        | 1%                                  | (0 - 5)%  |                                 |                                       |

G=number of groups/arms in analysis; P=number of patients in analysis

\* Duration greater than 28 days or requiring intervention

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

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## ***Abbreviations and Acronyms***

|              |   |  |
|--------------|---|--|
| AUA          | = | American Urological Association                    |
| AUS          | = | artificial urinary sphincter                       |
| CI           | = | confidence interval                                |
| etc.         | = | et cetera; and the rest                            |
| et al.       | = | and others   |
| FDA          | = | Food and Drug Administration                       |
| G            | = | groups   |
| i.e.         | = | that is  |
| P            | = | patients   |
| PGC          | = | Practice Guidelines Committee                      |
| RCT          | = | randomized controlled trial                        |
| sine qua non | = | an essential or indispensable element or condition |
| SUI          | = | stress urinary incontinence                        |
| U.S.         | = | United States                                      |
| w/           | = | with   |

## Chapter 2. Methodology

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This guideline used an explicit approach to address the relevant factors for choosing among alternative interventions.<sup>1</sup> These factors include outcomes of the interventions, patient preferences, and the relative priorities of interventions given limited health care resources. In developing the guideline, the Panel used scientific evidence to estimate outcomes of treatment modalities as accurately as possible. Panel members themselves served as proxies for patients in considering preferences with regard to health and economic outcomes.

The steps taken to develop this guideline are summarized in Chapter 1 and described in detail in the present Chapter. Steps included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval, and dissemination.



## **Problem Definition**

This update guideline was based on the original AUA guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997. The methodology was similar to that used in the previous guideline. Like the previous guideline, the analysis was limited to surgical treatments. Non-surgical therapies such as biofeedback, pessaries, and pelvic floor exercises were not examined. Unlike the previous guideline, the update includes an analysis of patients who also received surgical therapy for prolapse although it doesn't attempt to compare their efficacy. This update is also restricted to therapies introduced since the last guidelines report and to the therapies that appeared to be the most efficacious in the previous guideline.

Like the previous guideline, the intention was to determine the impact of the various available treatments on the outcomes of importance to patients. The efficacy outcomes examined were resolution, improvement, and recurrence of incontinence and urgency. The panel also examined the impact of treatment on prolapse resolution, and post-operative recurrence or new onset. However, insufficient usable information was available to make meaningful estimates for these prolapse outcomes. The panel also attempted to estimate the occurrence of side effects and complications of treatments. Incontinence treatments analyzed included retropubic suspensions, slings, injection therapy, and artificial sphincters. The panel excluded treatments that were not generally available in the US and were not expected to be approved for general use by the time of the release of the guideline. The panel also decided not to update outcomes for treatments that were covered in the previous guideline, namely anterior repairs and transvaginal suspensions, but were no longer considered contemporary surgical treatments. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. A wide variety of procedures were used

correct prolapse including hysterectomy, and position specific repairs (e.g. anterior, posterior, enterocele, and apical).

## **Literature Search and Data Extraction**

The review of the evidence began with a literature search and data extraction. Articles were selected from a database, based on articles retrieved for the previous guideline and a series of four Medline searches beginning in December 2002 and concluding in June 2005. The searches were limited to human subjects, English language, publication date on or after 1990, and the mesh term “female”. Searches were containing the mesh heading “urinary incontinence, stress”. Additional searches were done using the terms “urinary incontinence, stress”, “stress incontinence”, and “urinary-incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance. The abstracts were reviewed by the panel chairs and articles were selected for data extraction if any chair felt it might have useful data. In total 1302 citations entered the extraction process. A data extraction form was developed, tested and revised (see appendix A4. The panel was trained in data extraction. After double review and quality control of the initial extractions, single panel members extracted data from the articles with over 25% cross checked by another panel member. The final versions of the extracted data were entered into a Microsoft Access® (Microsoft, Redmond, WA) database. The Panel met in person and via conference calls to review the extracted data. Inconsistencies in data recording were reconciled, extraction errors were corrected, and some articles were excluded. Reasons for excluding articles from further analysis were as follows:

1. The article did not provide usable data on the outcomes of interest.

2. The article did not deal with stress incontinence, e.g. articles that dealt with patients who only had prolapse.
3. The article dealt only with basic science or epidemiology.
4. The treatments used were not current or were not the focus of the analysis.
5. The article was a review article or reported data reported elsewhere.
6. The treatment discussed was not available in the US or expected to be available when the guideline was scheduled for release.

A total of 436 of the articles were accepted. An additional 155 articles were accepted for complications data only. These 155 articles were otherwise acceptable but had insufficient follow-up for efficacy outcomes. Articles were only accepted for efficacy data if there was a minimum follow-up of at least 1 year. A complete list of the articles used is in Appendix A5, ordered by primary author, and in Appendix A6, ordered by reference number. Note that some articles excluded from evidence combination remained candidates for discussion in the text of the guideline.

## **Evidence Combination**

The analytic goals were expanded from the previous guideline. However, as mentioned above two patient groups were analyzed, one where no patients received treatment for prolapse, and another where some or all received prolapse repairs. To generate an outcome table, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Such a combination can be performed in a variety of ways depending on the nature and quality of the evidence. For example, if there is one good randomized controlled trial, the results of that trial alone may be used in the outcome table while findings of other studies of lesser quality are

ignored. Alternatively, if there are no studies of satisfactory quality for certain outcome table cells or if available studies are not commensurable, expert opinion may be used to complete those cells. Finally, if a number of studies have some degree of relevance to a particular cell or cells, then meta-analytic mathematical methods may be used.

A variety of specific meta-analytic methods are available, and selection of a particular method depends on the nature of the evidence. For this *guideline*, the panel elected to use the confidence profile method,<sup>2,3</sup> which provides methods for analyzing data from studies that are not randomized controlled trials. The Fast\*Pro computer software<sup>4</sup> was used in the analysis.

Although a number of randomized controlled trials were uncovered in the literature search, there were insufficient numbers on the same topic to warrant meta-analysis. Discussions of the results of some of these trials are included where relevant in the text of this document. Meta-analysis was performed using the individual arms of the controlled trials and the clinical series where similar patients were similarly treated. The Fast\*Pro software was used to perform the meta-analyses. Series that were combined frequently showed very different results implying site-to-site variations that may have resulted from differences in patient populations, in how the intervention was performed, or in the skill of those performing the intervention. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

A random-effects model assumes that there is an underlying true rate for the outcome being assessed for each site. It further assumes that this underlying rate varies from site to site. This site-to-site variation in the true rate is assumed to be normally distributed. The method of meta-analysis used in analyzing the data attempts to determine this underlying distribution.

The results of the confidence-profile method are probability distributions that are described using the median of the distribution with a confidence interval. In this case, the 95% confidence

interval indicates that the probability (Bayesian) of the true value being outside the interval is 5%. These Bayesian confidence intervals are sometimes called credible intervals.

The Bayesian method of computation assumes a “prior” distribution that reflects knowledge about the probability of the outcome before the results of any experiments are known. The prior distributions selected for this analysis are among a class of “noninformative” prior distributions, which means that they correspond to little or no prior knowledge. The existence of such a prior distribution can cause small changes in results, particularly for small studies. The prior distribution for all probability parameters is Jefferey’s prior (beta distribution with both parameters set to 0.5). The prior for the variance for the underlying normal distribution is gamma distributed with both parameters set to 0.5.

In addition to the outcomes table, some graphs showing the results were developed to visually show some treatment differences.

It is important to note that, for certain outcomes, more data were reported for one or another treatment modality. While resulting confidence intervals reflect available data, the probabilities for certain outcomes can vary widely from study to study within one treatment modality. For example, differences in patient selection may have had more weight in analyses than differing treatment effects. Nevertheless, the results obtained reflect the best outcome estimates presently available.

## **Patient Groups**

The panel attempted to evaluate outcomes based on a variety of patient characteristics including type of incontinence, previous treatment, presence of prolapse, prior pregnancy and severity of incontinence. However, in most cases, the outcomes data were not fully or consistently stratified by these conditions. Ultimately, patient groups were divided into 2

categories: groups where no patients received treatment for prolapse (comparable to the previous guideline) and groups where some or all patients received treatment for prolapse. Note that the distinction is based on treatment received, not on whether the women in the groups demonstrated prolapse. The panel desired to analyze the data based on whether or not patients had only stress incontinence or also evidenced prolapse. The data could not be analyzed in that manner since few studies stratified results in that manner. It was also not possible to find many groups of patients where all patients received prolapse treatment to enable a clean distinction between no prolapse treatment and those receiving incontinence treatment plus prolapse treatment.

## **Treatments**

The panel considered a wide variety of treatments (see extraction form, appendix A4). As mentioned above, treatments shown to be less efficacious by the previous guideline were not extracted and analyzed (anterior repairs and trans-vaginal needle suspensions). However, limited data were available for many of the treatments of interest. In some articles, patients were treated by a variety of treatments but the outcomes weren't stratified by treatment. These articles were ultimately rejected.

## **Efficacy Analysis**

The outcomes analyzed for efficacy included two levels of continence: cured/dry and cured/dry/improved. The first level includes patients reported as dry or totally cured. The second level also includes patients reported as improved. The percent of patients with each

condition were meta-analyzed. Credible intervals (Bayesian confidence intervals) were produced as well.

Urgency was also analyzed. Since not all patients had pre-operative urgency, an attempt was made to estimate urgency based on whether a patient had urgency prior to treatment. Patients were divided into three categories: 1) without pre-existing urgency, 2) with pre-existing urgency, and 3) unknown or uncertain pre-existing urgency. These categories are labeled 1) new onset, 2) pre-existing, and 3) unspecified in the outcomes tables. Urgency was further subdivided by type of post-operative urgency. The categories are 1) urge incontinence, 2) urge symptoms, and 3) unspecified for patients who have actual urge incontinence, urge symptoms alone, or unknown or unspecified urgency respectively. Again, the results are reported as the percent of the relevant patient group having each outcome.

The panel desired to estimate the impact of treatment on prolapse, both the resolution of existing prolapse and the development of new prolapse. However, the data extracted were insufficient to allow a meaningful analysis of these outcomes.

## **Complications**

Different studies report complications grouped differently. They also use different names for similar complications. The panel grouped complications to try to include all similar complications. Only studies that specifically reported data concerning occurrences of complications were included in the analysis of complications. The panel did not assume that the lack of reporting implied the lack of occurrence of any specific complication. Although investigators may not have reported complications that did not occur, combining complications reduces the possibility of overestimating the complication rate. The probability that a patient will have a complication probably is still overstated slightly because some patients experience multiple complications. Thus, the result of the meta-analysis is best interpreted as the mean

number of complications the patient may experience rather than as the probability of having a complication. There were insufficient data to permit meaningful meta-analyses of patient deaths. The estimates of death rates provided in the guideline are the Panel's expert opinion based on the limited data available.

Retention was given special attention by the panel. A special section of the extraction form was dedicated to assessing retention and its duration. Unfortunately, there was some confusion during the extraction process. Retention data were not extracted in some cases where the follow-up for efficacy outcomes was less than 1 year. This was discovered too late in the process to go back and extract the additional data. In order to be consistent and avoid bias, data were only included in the analysis from studies with 1 year or greater follow-up. The panel examined the possibility of trying to estimate the probability of retention lasting various lengths of time. Insufficient data were available to analyze retention duration in any substantial way. The panel finally decided to estimate the probability that a patient had significant retention. Significant retention was defined as retention lasting 4 weeks or longer or retention requiring treatment (e.g. cutting a sling or otherwise modifying the original operation).

## **Guideline Generation and Approvals**

After the evidence was combined and outcome tables were produced, the Panel met to review the results and identify anomalies. Additional teleconferences were held to review updates to the outcomes tables based on the problems identified. From the evidence in the outcome tables and expert opinion, the Panel drafted the treatment guideline. The draft was sent to 76 peer reviewers of whom 24 provided comments; the Panel revised the document based on the comments received. The guideline was submitted for approval first to the Practice Guidelines Committee of the AUA. Then it was forwarded to the Boards of Directors for final approval.



## **Dissemination**

The guideline is published on the web site for the American Urological Association. A version of Chapter 1 will be published in the *Journal of Urology*.

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## Chapter 3: Outcomes Analysis for the Surgical Management of Stress Urinary Incontinence

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## Introduction

This chapter provides the results of the Panel's review of the literature and analysis, presented in outcomes tables, as well as discussions of the outcomes. Two sets of outcomes tables are provided including one set for patients who were treated only for stress incontinence and another set for patients who received treatment for both stress incontinence and some form of pelvic organ prolapse. Since some reports did not segregate patient data accordingly, for the purposes of this analysis if any patient in a group received concomitant prolapse surgery the entire group was included in the category.

Outcomes estimates are presented in two cells for each estimate; the first contains the number of groups of patients followed by the total number of patients (G/P) included in the meta-analysis. A group of patients usually represents the patients in a single study that the received indicated treatment(s). However, if a study had multiple groups with varying factors (e.g. degree of incontinence, details of the procedure used) these patients were analyzed as a separate group in the meta-analysis. In the second cell, the bolded percentage indicates the best estimate of the rate of occurrence of an outcome (median of the Bayesian posterior from the meta-analysis) followed by the 95% credible interval (Bayesian confidence interval) for that estimate. These numbers represent the best estimates that can be made from the existing data and served as the primary basis for the guideline statements presented in Chapter 1.

## **Efficacy Outcomes**

### **Resolution of Stress Incontinence**

The main efficacy outcome was the resolution of the stress incontinence. Cured and dry (cure/dry) was defined by the Panel as the complete resolution of symptoms with no residual leakage under normal and stress situations. Patients reported as having incomplete improvement were considered cure/dry/improved. There were inconsistencies in the reporting of these outcomes in the literature, with some authors distinguishing cured patients from improved patients and others reporting only those cured or improved/cured. The Panel accepted the author's representation (i.e. if a report indicated that a group of patients was cured they were counted as cured) but it is likely that not all patients counted in the cure/dry category were truly dry. If the author defined cured to include some degree of leakage, the patients were counted in the cure/dry/improved category only.

The outcomes were analyzed separately according to the method of incontinence assessment; the "subjective" outcome category included primarily patient reports and diaries and the "objective" outcome category included a variety of formal tests including urodynamics. A separate category ("any") was created for studies that didn't clearly specify how an outcome was assessed or for those using a mixed collection of measures. To make this "any" category complete, outcomes from all studies were included. If a study reported both subjective and objective outcomes, then the subjective outcomes were included in the "any" analysis. If a study reported outcomes from a variety of subjective measures, the one with the highest number of patients was used for both the subjective and "any" analyses.

The outcomes were analyzed by time of last assessment with the following intervals: 12–23 months, 24–47 months, and 48 months or more. If a study reported results for multiple times within one of these ranges, reports closest to 18, 36, and 60 months respectively were used. In this analysis, only studies that had a 12 month minimum follow-up were included; this is in contrast to the 1997 guideline<sup>1</sup> in which studies with a follow-up of less than 12 months were included if the minimum of the range was at least 12 months or the mean or average follow-up was at least 24 months.

Appendices A12-A16 show the results for patients who had no concomitant prolapse surgery for the time intervals 12–23 months, 24–47 months, and greater than 48 months, respectively. Appendices A7 – A11 are arranged similarly and show data for patient groups in which some or all of the patients had concomitant prolapse treatment. Treatments with no available data in are excluded from the tables; thus, not all treatments are presented in all tables.

## **Urgency**

The Panel recognizes the importance of the relationship between surgery for SUI, the complaint of involuntary leakage on effort, exertion, sneezing or coughing (as defined by the International Continence Society [ICS])<sup>2</sup> or with physical exertion (as defined by the National Institutes of Health)<sup>3</sup> and other lower urinary tract symptoms (LUTS; defined as storage, voiding, and postmicturition symptoms by the ICS). OAB syndrome is comprised of the main storage symptoms of LUTS and is defined by the ICS as urgency (the complaint of a sudden, compelling desire to pass urine which is difficult to defer or a strong need to pass urine for fear of leakage (NIH), with or without urgency urinary

incontinence (UUI; involuntary leakage accompanied by or immediately preceded by urgency), usually with frequency and nocturia, in the absence of pathologic or metabolic factors that would explain these symptoms.<sup>2</sup>

The Panel accepted the author's use of "urge", "urge incontinence" or "urgency" with or without "incontinence" without requiring specific adherence to these definitions. The Panel attempted to distinguish those patients having urge incontinence from those having symptoms of urgency alone in the absence of urge incontinence. However, this distinction was not always reported. Three categories of studies were analyzed: 1) those that included patients with urge incontinence alone; 2) those that included patients with urgency symptoms alone; and 3) those that included patients with unspecified urgency or that combined patients with incontinence and urgency symptoms. Because urgency can occur with stress incontinence and is often resolved with treatment of stress incontinence, the data for urgency are listed in the efficacy section of this chapter; however, urgency occurring de novo after incontinence surgery could also be considered a complication of the treatment. A third category was analyzed for studies not reporting the preoperative urgency status of patients with postoperative urgency and those in which patients with and without preoperative urgency were combined.

Appendix A15 provides the results of the Panel's analyses of urge incontinence, urgency symptoms alone, and unspecified urgency for patients who did not receive concomitant prolapse surgery. Appendix A10 provides the same outcomes in the group of patients where some or all had concurrent prolapse repair. Each table contains three data sets corresponding to 1) continuing urgency in patients with pre-existing urgency; 2) de

novo urgency in patients who did not have preoperative urgency, and 3) unspecified or mixed cases. The format of each entry is the same as for stress incontinence resolution.

The success of surgery for decreased outlet resistance is intimately related to preoperative and postoperative storage and emptying function. The interrelationship of the individual symptoms comprising LUTS (storage and emptying), OAB or urgency/urgency incontinence and of the LUTS to the results of surgery is complex. Patients with SUI may experience no other LUTS or may develop one or more symptoms postoperatively. Alternatively, patients with one or more preoperative LUTS may have symptoms that independently improve, persist, or worsen. In addition, the de novo development, improvement or worsening of symptoms may be acute (temporary) or chronic (permanent). These symptoms may also increase (aging of population, comorbidities) or decrease (resolution of perioperative alterations) over time.

The Panel recognizes the symptoms of “urgency” and “urgency urinary incontinence” as the most commonly reported and most representative of pre-existing or de novo lower urinary tract storage symptoms. Although preoperative cystometry was performed in some studies, postoperative urodynamics were rarely performed in patients regardless of symptoms; thus, patient results are almost universally reported based on symptoms. It is recognized that the symptoms of urgency or UUI may or may not correlate with the urodynamic (cystometric) finding of detrusor overactivity. Additionally, patients may experience detrusor overactivity that is provoked by effort or exertion, or may experience detrusor overactivity without sensation, further confounding the diagnosis and therapy.



Table 1 provides data on patients experiencing postoperative urgency or urge incontinence from the 1997 review<sup>1</sup> and from the current analysis, although these data aren't directly comparable in that the 1997 analysis examined the correlations between urgency and detrusor instability. As mentioned above, the present analysis focused on the development of de novo urgency and urge incontinence and separately analyzed the resolution of these symptoms patients with the presence of urgency and urge incontinence.

OAB is common in women with SUI, occurring in 30%–50% of cases<sup>4</sup>, with surgical treatment of SUI often offering resolution of OAB.<sup>5,6</sup> Unfortunately, persistence of OAB after SUI surgery has been reported in up to 40% of patients.<sup>7,8</sup> Persistent OAB has been reported to complicate 8%–25% of all sling procedures,<sup>9</sup> as well as 7.6%–12% of TVT procedures and 1.4%–16.6% of retropubic urethropexies.<sup>10-12</sup> In the present analysis, persistence of urgency occurred in approximately 15% of those receiving suspension procedures and about 30% of those receiving sling procedures. Moreover in 7%–21% of cases, de novo OAB may occur.<sup>7,13-16</sup> Possible risk factors for de novo OAB include undiagnosed preoperative OAB, increased bladder wall thickness (induced by or associated with resultant changes in bladder afferent and/or efferent neuromuscular behavior), bladder neck dissection, greater patient age, and postoperative urethral obstruction.<sup>14</sup>

## Complications

Complications were analyzed similarly to the efficacy outcomes. Because of the wide variation in terms used to describe complications, the Panel grouped complications

together that represented similar or related outcomes (See Appendix A17 for complications groupings). As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Outcomes tables were developed for each group of complications, with separate tables created for the population of patients receiving or not receiving concurrent prolapse treatment. The format of the tables is the same as for the efficacy tables, but the layout is reversed. The treatments are across the top for complications and down the left side for the others.

## **Retention**

The Panel defined retention as catheter-dependency for greater than 28 days postoperatively and/or the need to undergo an intervention to correct retention following surgery. Using these definitions, retention estimates ranged from 1%–9% in the population without prolapse treatment and from 1%–10% in the population with concurrent prolapse treatment (Appendices A9 and A14). As a group, those undergoing retropubic procedures had retention estimates of 4% for the non-prolapse group and 1% for the prolapse group. Patients undergoing sling procedures were more likely to experience retention with the highest rates observed in those undergoing synthetic slings at the bladder neck without bone anchors. In these groups, the estimates were 9% and 10% for the non-prolapse treatment and the prolapse treatment populations, respectively. The lack of a standardized definition of retention and the failure of many studies to provide data regarding postoperative urinary retention were limitations to this analysis. Yet, from the present analysis it may be concluded that retention affects 1%–10% of

women postsurgically and varies by procedure, with sling procedures having higher rates of retention than retropubic procedures.

## **Genitourinary Complications**

With regard to genitourinary complications, the Panel analyzed these events as intraoperative complications (events occurring during the surgical procedure or in the immediate perioperative period) or other complications (events occurring after the immediate perioperative period). The purpose of this distinction was to identify complications that may be unique to the technical aspects of a particular procedure or complications that may be related to the consequences of or materials utilized in the procedure.

## **Intraoperative complications**

Bladder injury was reported with 3%–8% of procedures (Appendices A11 and A16).

Although the overall incidence was low, it appeared that bladder injury was more frequent in patients receiving SUI procedures with concomitant prolapse repair. This trend may be the result of the more extensive dissection needed when doing a simultaneous prolapse repair, however the trend did not reach significance and therefore may be not representative of actual experience as well. In addition, the risk of bladder injury was somewhat higher (not statistically significant) in procedures utilizing synthetic materials at the midurethra, particularly when compared to autologous slings and retropubic suspensions. This finding may have been a result of more stringent data recording in the use of synthetic materials or possibly related to technical aspects of

certain midurethral slings. Trocar placement into the retropubic space in the absence of advanced mobilization of the bladder and urethra may predispose to a higher incidence of bladder and urethral injury. Urethral injury was only identified in association with synthetic slings placed at the midurethra or laparoscopic retropubic suspensions. This may be related to technical aspects of the midurethral sling procedure that may predispose to these types of injuries. However, the small cohort of patients did not allow a direct comparison with other procedures. Ureteral injuries occurred during less than 5% of the procedures in most series; however, they were reported in 4%–11% of laparoscopic suspensions, which seemed to the Panel to be higher than expected based on their experience. Many of the reported cases of laparoscopic suspensions reflected the early experiences of surgeons and perhaps this could explain the increased risk of laparoscopic suspensions when compared with other procedures.

### **Other complications**

With the many different techniques and materials utilized in the surgical correction of SUI, surgeons must remain diligent in obtaining long-term outcomes data to understand the effects of these techniques and materials on quality-of-life and potential complications. Of major contemporary concern is the resurgence of the use of mesh materials in the surgical correction of SUI, particularly with the recent emergence of the tension-free midurethral sling procedures using synthetic materials. Early experience with synthetic mesh materials in pubovaginal sling and prolapse surgeries was associated with a considerable risk of mesh complications. Erosion rates of 20%–30% were reported in patients following implantation of Dacron™, Mersilene™, and Marlex™ mesh

materials.<sup>17-19</sup> In these early procedures, larger incisions with more extensive dissection may have increased the potential for bacterial exposure, and increased tension may have promoted tissue ischemia. The woven, multifilamentous nature of these mesh materials may have limited the ingrowth of host tissue, leading to erosions, draining sinuses, and fistulas. These early experiences forced many surgeons to abandon the use of synthetic material in pelvic reconstructive surgery.

The success of the TVT procedure introduced surgeons to several principles that have seemingly facilitated the safe use of synthetic material in pelvic reconstruction. The use of small incisions and minimal dissection decreases the potential for bacterial exposure. The avoidance of tension on the mesh material limits local tissue ischemia while the use of macroporous monofilament mesh materials promotes host tissue ingrowth and biocompatibility. Incorporating these principles, the synthetic tension-free slings have become one of the more commonly used procedures in the surgical management of SUI. The reported incidence of mesh erosions and complications with these procedures appears quite low, although the true incidence is not known. A recent report analyzing the United States Food and Drug Administration Manufacturer and User Facility Device Experience database (U.S. FDA MAUDE)<sup>20</sup> which collects data on U.S. FDA approved medical devices, suggests that these complications are indeed underreported.<sup>21</sup> In addition to mesh materials, permanent suture materials, tacking devices and laparoscopic instrumentation may also be associated with lower urinary tract or vaginal injuries.

Erosions and extrusions may also occur with the use of foreign materials such as mesh. For the purposes of this review, the Panel has defined erosion as the presence of a

foreign body in the lumen of the urinary tract (bladder, urethra or ureter) whereas extrusion was defined as the exposure of mesh in the vagina. Urinary tract erosion has been reported subsequent to all SUI procedures, but overall this does not appear to be a common event. In this meta-analysis (Appendices A11 and A16), erosion into the urethra and bladder occurred following 2%–4% of vaginal sling procedures. Erosions appear to occur more frequently following synthetic sling procedures; however, the method of reporting varies widely. Some authors have reported that “erosions” occurred but were not specific as to location and type. For example, 17% of erosions resulting from synthetic slings placed at the bladder neck were not classified. The incidence of urethral and bladder erosions appears to be higher following placement of synthetic slings at the bladder neck when compared to autologous slings. These data might suggest that synthetic slings have a higher rate of erosion than autologous or cadaveric slings. Based on these findings, the Panel believes that discussion of urinary tract erosion should be part of the informed consent process, particularly when selecting synthetic slings. The Panel also concludes that urinary tract erosion is a risk of any surgical procedure used in the treatment of SUI, with the risk appearing highest for synthetic slings, particularly when placed at the bladder neck.

Vaginal extrusion occurred in 1-8% of cases following synthetic slings. In this meta-analysis, the unexpectedly high risk of vaginal extrusion associated with cadaveric slings (23%) probably represents an anomaly resulting from the fact that few studies of cadaveric slings mentioned extrusion and the one study reporting this complication was small. Since the small number of series may affect the overall data reporting and incidence rates, this result is likely artifactual.

## **General Medical Complications**

General medical complications captured in this analysis included cardiovascular, dermatologic, febrile, infectious (local, systemic, and urinary tract), neurologic, and pulmonary complications as well as subjective complications such as pain and sexual dysfunction (Appendices A11 and A16). In addition, transfusion was analyzed as a separate category. There was variable and limited reporting of most general medical complications, with many authors not reporting any complications data. These findings reinforce the need for standardized reporting of complications, particularly as related to general medical complications.

Urinary tract infections were the most commonly reported infectious complication, with estimates following retropubic surgery of 13% for those not undergoing concurrent prolapse procedures and 17% for those receiving such procedures. Patients undergoing sling procedures were less likely to experience urinary tract infection, with estimates of 4%–16% for the no prolapse treatment groups and 1%–9% for the prolapse-treatment group. However, the majority of authors did not report specifically on the presence or absence of urinary tract infections and caution must be used in interpreting these data.

There was very little uniformity in reporting other infectious complications. Febrile morbidity estimates were between 0%–14% of patients depending upon the procedure. The highest estimates were noted in the retropubic groups with rates of 8%–11% for the non-prolapse and prolapse treatment groups, respectively. Patients undergoing sling procedures were less likely to have a febrile morbidity reported and this

was true for both treatment groups. The reported estimates of febrile morbidity ranged in those populations between 2%–8%.

Dermatologic complications were reported only in patients receiving injectable collagen, with an estimate of 5%. The estimates for sexual dysfunction were 4% for retropubic suspensions and 8% for autologous fascial slings. However, the definitions and reporting methods for identifying sexual dysfunction remain extremely variable in the evidence as assessed. Therefore the rates reported may not be representative of the true incidence of this outcome. Standardization of reporting indices is critically needed for a better understanding of the true rates of sexual dysfunction arising from interventions for stress incontinence and pelvic organ prolapse.

## **Operative Complications**

### **Gastrointestinal complications**

All procedures performed adjacent to the peritoneal lining and its contents are associated with risks of injury to the bowel and such injuries have been reported with open, laparoscopic and “minimally invasive” procedures. “Minimally invasive” synthetic-based retropubic procedures had the highest reported risk of bowel complications, with estimates of 1% for synthetic midurethral slings performed without concomitant prolapse repair (see Appendix A16). There were too few reports of bowel injuries resulting from the other procedures for a meaningful comparison.



### **Vascular complications**

Vascular complications were defined as any reported iatrogenic intraoperative injury to a specific major or significant blood vessel not including intraoperative or postoperative bleeding or hematomas. The estimates for vascular complications are found in Appendices A11 and A16. There were no reported vascular complications in over 400 articles reviewed for this meta-analysis involving an anti-incontinence procedure with or without pelvic organ prolapse repair in approximately 40,000 patients. Yet, it is well known that major vascular injuries including iliac, femoral, obturator, and epigastric vessel injury have been reported with the TVT procedure in the FDA MAUDE database.<sup>20</sup> The Panel believes that the risk of serious vascular complications with TVT procedures is very low; but nevertheless surgeons should bear this risk in mind when performing this technique.

### **Neurologic complications**

Neurologic complications occurring in association with SUI surgery are rare (see Appendices A11 and A16). A total of five cerebrovascular accidents (CVA) were reported. CVA occurred more frequently in patients undergoing retropubic suspensions (n=3) versus pubovaginal slings (n=1) or midurethral slings (n=1), although the small numbers of these events preclude statistical analysis. No patient required additional surgery as a result of a CVA but CVA was the cause of death in three patients. While all of the CVAs may be attributable to the patient having had an anesthetic and/or surgery, one must take into consideration the age and other comorbidities of patients who elect surgical correction of SUI.

Twelve nerve injuries were reported. In some cases these were listed only as “nerve injury” whereas in other reports they were described by the resulting deficit or as an injury to a discrete nerve. The most common nerve injury cited was to the obturator nerve, which occurred in three patients. There were nerve injuries described with the use of midurethral synthetic slings (n=5); however, none of these patients required additional surgical procedures. Two patients required additional surgical procedures to treat complications related to nerve entrapment. One patient had removal of a suture and a second patient underwent removal of a bone anchor using a hammer and osteotome.

### **Infectious complications**

The panel elected to divide infectious complications into multiple subsets to accommodate the various definitions presented in the literature; these included infection (undefined), infection with local extension, abscess, and osteomyelitis (see Appendices A11 and A16). Osteomyelitis, rarely reported, was observed in procedures with and without bone anchors.

### **Death**

The risk of perioperative mortality following surgical treatment of SUI is very low, although a precise estimate is difficult to achieve due to the paucity of studies that specifically evaluate mortality, compounded by the fact that published studies represent only a tiny fraction of all surgical procedures performed. To gain an estimate of perioperative mortality in the SUI patient population, a combined approach was taken: 1) the raw data from the current analysis were assessed; 2) a Medline search was performed

using the term “perioperative mortality” and reports were obtained for all surgical procedures in the U.S. and also for surgical procedures thought to be of comparable risk to SUI surgery; and 3) reports were obtained that specifically dealt with surgical procedures for SUI and urogynecology (shown in Table 2<sup>22-29</sup>). Finally, an estimate was determined for the added perioperative mortality from the special circumstances of vascular or bowel injury due passage of trocars from midurethral sling kits.

In contemporary series, overall perioperative mortality for all surgical procedures ranged from 0.02%–1.8% (Table 2). In the Medline search on which this review was based, there were three deaths out of 39,019 patients, for a mortality rate of 0.008%. Waetjen et al<sup>26</sup> reported an unadjusted mortality rate of 0.01% in a survey of 135,000 women undergoing incontinence surgery in the U.S. in 1998. However, in that series pubovaginal slings accounted for less than 15% of the procedures; nearly three-quarters had either retropubic suspension or anterior repair. This is probably an underestimation of mortality due to bowel or vascular injury from trocars. No other reports that dealt specifically with mortality after incontinence surgery were identified. Sung et al<sup>29</sup> reported an unadjusted risk of death following all urogynecologic procedures of 0.04% and noted that mortality rate increased with age. For women less than 60 years of age, the mortality rate was 0.01%; for those more than 80 years of age it rose to 0.28%. The authors noted that elderly women had a 13-fold increase in the risk of death and a 33% higher risk of suffering postoperative complications compared with younger women, irrespective of their co-morbidities.<sup>29</sup> Brown et al<sup>27</sup> reported a perioperative mortality of 0.03% after pelvic organ prolapse surgery. In a study of surgical mortality, Pine et al<sup>28</sup> reported mortality rates for various surgical procedures. The Panel selected those that

were the most comparable to incontinence surgery for a comparison of perioperative mortality data. The unadjusted mortality rates were 0.11%, 0.41% and 0.20% for hysterectomy, herniorrhaphy, and prostatectomy, respectively (Table 2).

Finally, the Panel estimated the minimal mortality after the TVT procedure by accessing the US FDA MAUDE Database<sup>20</sup> (now known as MedWatch) using the terms “TVT,” “transvaginal tape,” “sling,” “pubovaginal sling,” and “suburethral sling” which yielded incident reports that included six deaths. Three of the deaths were associated with bowel perforations and one each resulted from hemorrhage, myocardial infarction and pulmonary embolism. In addition, Panel members have documented at least two other deaths due to vascular injury.

In summary, perioperative mortality after sling surgery in the index patient is low; the Panel estimates it at between 0.01%–0.09%. However, mortality increases with advancing age and comorbidities, with mortality nearly three per 10,000 in patients over 80 years of age. Blind passage of trocars into the retropubic space potentially increases the possibility of bowel or vascular injury that could lead to mortality.

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1 **Table 1. Patients experiencing postoperative urgency or**  
 2 **urge incontinence**

|  | Retropubic<br>Suspensions |                          | Transvaginal<br>Suspensions |                          | Sling Procedures |                          |
|--|---------------------------|--------------------------|-----------------------------|--------------------------|------------------|--------------------------|
|  | G/P                       | Median CI<br>(2.5-97.5%) | G/P                         | Median CI<br>(2.5-97.5%) | G/P              | Median CI<br>(2.5-97.5%) |
| <b><i>Prior Analysis<sup>1</sup></i></b> |                           |                          |                             |                          |                  |                          |
| Urgency                                  |                           |                          |                             |                          |                  |                          |
| + urgency/+DI*                           | 6/78                      | 66 (50–79)               | 6/33                        | 54 (35–73)               | 4/45             | 46 (24–68)               |
| + urgency/–DI*                           | 6/319                     | 36 (22–52)               |                             |                          | 5/110            | 34 (13–61)               |
| – urgency/+DI*                           | 1/6                       | 4 (0–33)                 | 1/3                         | 7 (0–54)                 | 4/36             | 20 (5–45)                |
| – urgency/–DI*                           | 8/241                     | 11 (8–16)                | 6/150                       | 5 (3–10)                 | 7/140            | 7 (3–11)                 |
| <b><i>Current Analysis</i></b>           |                           |                          |                             |                          |                  |                          |
| Urge Urinary<br>Incontinence             |                           |                          |                             |                          |                  |                          |
| New Onset                                |                           | 10-14                    |                             |                          |                  | 11-22                    |
| Pre-existing                             |                           | 22-48                    |                             |                          |                  | 29-52                    |
| Urgency                                  |                           |                          |                             |                          |                  |                          |
| New Onset                                |                           | 9-11                     |                             |                          |                  | 13<br>(Grade>1)          |
| Pre-existing                             |                           | 40<br>(Grade<1)          |                             |                          |                  | 21<br>(Grade>1)          |

3 \* Preoperative status

4 Abbreviations: CI, confidence interval; DI, detrusor instability; G/P, number of groups and number of  
 5 patients per treatment arm

1 **Table 2. Estimated perioperative mortality for SUI and**  
 2 **urogynecologic surgical procedures**

3

| Surgical procedure                                  | Mortality rate |
|---|----------------|
| Overall perioperative mortality <sup>22-25,28</sup> | 0.02 – 1.8%    |
| Stress incontinence <sup>26</sup>                   | 0.01%          |
| Urogynecology <sup>29</sup>                         | 0.04%          |
| < 60 years  | 0.01%          |
| 61 – 69 years                                       | 0.05%          |
| 70 – 79 years                                       | 0.09%          |
| > 80 years  | 0.28%          |
| Hysterectomy <sup>28</sup>                          | 0.11%          |
| Pelvic organ prolapse <sup>27</sup>                 | 0.03%          |
| Herniorraphy <sup>28</sup>                          | 0.41%          |
| Prostatectomy <sup>28</sup>                         | 0.20%          |

4



## ***Appendix A1: Female Stress Urinary Incontinence Clinical Guidelines Panel, Consultants and Data Extractors (1997)***

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**Appendix A3 - Article Staus Report**  
**American Urological Association, Inc.**  
**SUI Guidelines Update Panel**

**November-09**

| <b>Literature Search</b> | <b>Articles<br/>Retreived</b> | <b>Selected<br/>for Extraction</b> | <b>% of Lit Search / Total</b> |
|--------------------------|-------------------------------|------------------------------------|--------------------------------|
| Original Guideline       | 1,069                         | 101                                | 9%                             |
| December, 2002           | 4,943                         | 942                                | 19%                            |
| May, 2004                | 787                           | 162                                | 21%                            |
| December, 2004           | 134                           | 60                                 | 45%                            |
| Jun, 2005                | 176                           | 37                                 | 21%                            |
|                          | 7,109                         | 1,302                              | 18%                            |

| <b>Data Entry</b> | <b>Articles</b> | <b>% Selected<br/>for Extraction</b> |
|-------------------|-----------------|--------------------------------------|
| Entered           | 1,302           | 100%                                 |
| in Process        | 0               | 0%                                   |
|                   | 1,302           | 100%                                 |

| <b>Article Status</b> | <b>Articles</b> | <b>% Data Entered</b> |
|-----------------------|-----------------|-----------------------|
| Accepted              | 436             | 33%                   |
| CX data only          | 155             | 12%                   |
| Rejected              | 866             | 67%                   |

| <b>Reasons for Rejection</b> | <b>Articles</b> | <b>% Total<br/>Rejected</b> |
|------------------------------|-----------------|-----------------------------|
| No Data                      | 292             | 34%                         |
| Insufficient Efficacy F/U    | 282             | 33%                         |
| RX not Current               | 124             | 14%                         |
| Not about RX                 | 100             | 12%                         |
| Basic Science                | 12              | 1%                          |
| Epidemiology                 | 4               | 0%                          |
| Other                        | 40              | 5%                          |
| Prolapse only                | 40              | 5%                          |
| Other Exclusion              | 264             | 30%                         |
| Duplicates                   | 5               | 1%                          |
| Panel Rejects                | 0               | 0%                          |

| <b>Analysis of Study Designs</b> | <b>Articles</b> | <b>Overall Number<br/>of Patients</b> |
|----------------------------------|-----------------|---------------------------------------|
| <b>Accepted Articles</b>         |                 |                                       |
| Case Series/Report               | 373             | 30,166                                |
| unknown at this time             | 16              | 4,295                                 |
| Controlled Trial                 | 31              | 2,833                                 |
| Case-control study               | 9               | 1,061                                 |
| Cohort Study                     | 5               | 449                                   |
| Opinion or Testimony             | 1               | 154                                   |
| Letter                           | 1               | 61                                    |
| <b>Total:</b>                    | <b>436</b>      | <b>39,019</b>                         |

| <b>Rejected Articles</b> | <b>Articles</b> |
|--------------------------|-----------------|
| not captured             | 730             |
| Case Series/Report       | 75              |
| Review/Policy            | 26              |
| Letter                   | 16              |
| Opinion or Testimony     | 6               |
| Controlled Trial         | 4               |
| Meta-analysis            | 4               |
| Other                    | 2               |
| Case-control study       | 1               |
| Cohort Study             | 1               |
| Database or Surveillance | 1               |
| <b>Total:</b>            | <b>866</b>      |

**Appendix A4- Extraction Form****American Urological Association, Inc.****Reference #** \_\_\_\_\_**SUI Guidelines Panel****Stress Urinary Incontinence  
Cover Sheets**

Citation: \_\_\_\_\_

Extractor A: \_\_\_\_\_ Date: \_\_\_\_\_

Extractor B: \_\_\_\_\_ Date: \_\_\_\_\_

Reconciliation Date: \_\_\_\_\_

**\_\_\_\_\_ ACCEPTED and Extracted**\_\_\_\_ Insufficient treatment efficacy follow-up  
Complications data only extracted

\_\_\_\_ Needs Panel Review

**1. Study Design**

\_\_\_\_ Case Series/Report  
 \_\_\_\_ Controlled trial  
 \_\_\_\_ Review/policy  
 \_\_\_\_ Case-control study  
 \_\_\_\_ Cohort Study  
 \_\_\_\_ Meta-analysis  
 \_\_\_\_ Data base or surveillance  
 \_\_\_\_ Letter: Ref. \_\_\_\_\_  
 \_\_\_\_ Opinion or testimony  
 \_\_\_\_ Other: spec. \_\_\_\_\_

**2. Are there particular difficulties with this study that make it less useful for our purposes (include study flaws and items that cause the study interventions or population not to match our needs)?**

\_\_\_\_ Serious design flaws (specify \_\_\_\_\_)  
 \_\_\_\_ Randomization failure  
 \_\_\_\_ Confounders present  
 \_\_\_\_ Selection bias  
 \_\_\_\_ Patient population not relevant  
 \_\_\_\_ Incomplete or biased statistics/data  
 Other: (describe) \_\_\_\_\_

\_\_\_\_ Blinding failure or insufficient  
 \_\_\_\_ Compliance problems (intensity)  
 \_\_\_\_ Cross-over problems  
 \_\_\_\_ Atypical intervention

**\_\_\_\_\_ REJECTED and not Extracted**

Article REJECTED due to (check all that apply):

\_\_\_\_ No relevant outcomes or complications data  
 \_\_\_\_ Insufficient treatment efficacy follow-up (must be > 12 months)  
 \_\_\_\_ Treatments not current (Stamey, etc.)  
 \_\_\_\_ Doesn't deal with treatment:  
     \_\_\_\_ Basic Science    \_\_\_\_ Epidemiology    \_\_\_\_ Other  
 \_\_\_\_ Purely Prolapse paper  
 \_\_\_\_ Other reason for exclusion:  
     specify: \_\_\_\_\_

Study Features (check all that apply)

\_\_\_\_ Retrospective  
 \_\_\_\_ Prospective  
 \_\_\_\_ Randomized  
 \_\_\_\_ Patient blinded  
 \_\_\_\_ Provider blinded  
 \_\_\_\_ Outcome evaluator blinded  
 \_\_\_\_ Cross-over

**3. Are there other data or points in this article that would be relevant that are not covered elsewhere?**

**Appendix A4- Extraction Form****American Urological Association, Inc.****Reference #** \_\_\_\_\_**SUI Guidelines Panel****Stress Urinary Incontinence  
Cover Sheets**

- 4. Study:** Total Patients enrolled: \_\_\_\_\_ (N)
- Country: \_\_\_\_\_ ☐ Check if multi-center/location
- Study Dates: \_\_\_\_\_ through \_\_\_\_\_ (leave blank if not specified)

**5. Group Definitions:**

| Group ID | Patients | Definition |
|----------|----------|------------|
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |
|          |          |            |

**6. Comments:**

- 7. Total time completing this extraction:** \_\_\_\_\_ minutes.

**Stress Urinary Incontinence****Group Characteristics****8. Group Characteristics**

Patients: N = \_\_\_\_\_

Age: \_\_\_\_\_

Mean: \_\_\_\_\_

Med: \_\_\_\_\_

Min: \_\_\_\_\_

Max: \_\_\_\_\_

**9. Coexistent Conditions**

|                        | Check | % | Num | Comments/Definition |
|------------------------|-------|---|-----|---------------------|
| Cystocele B-W I        |       |   |     |                     |
| II                     |       |   |     |                     |
| III                    |       |   |     |                     |
| IV                     |       |   |     |                     |
| Cystocele unspecified  |       |   |     |                     |
| Rectocele              |       |   |     |                     |
| Enterocoele            |       |   |     |                     |
| Uterine Prolapse       |       |   |     |                     |
| Vaginal Vault Prolapse |       |   |     |                     |
| Neurogenic Bladder     |       |   |     |                     |
| Urethrovaginal Fistula |       |   |     |                     |
| Urethral Diverticulum  |       |   |     |                     |
| Other                  |       |   |     |                     |
| Other                  |       |   |     |                     |

**10. Other Patient Characteristics**

|  | Check | % | Num | Comments/Definition |
|--|-------|---|-----|---------------------|
| Pts. With Prior Incont. Surgery        |       |   |     |                     |
| Mean Procedures/Pt.                    |       |   |     |                     |
| Hyst Unspecified                       |       |   |     |                     |
| Vag Hyst                               |       |   |     |                     |
| TAH                                    |       |   |     |                     |
| TAH+BSO                                |       |   |     |                     |
| TV BNS                                 |       |   |     |                     |
| RP BNS                                 |       |   |     |                     |
| Previous Prolapse Repair - unspecified |       |   |     |                     |
| Cystocele - unspecified                |       |   |     |                     |
| A. Anterior Repair                     |       |   |     |                     |
| B. Paravaginal Repair                  |       |   |     |                     |
| Rectocele                              |       |   |     |                     |
| Enterocoele                            |       |   |     |                     |
| Uterine Prolapse                       |       |   |     |                     |
| Vault Prolapse                         |       |   |     |                     |
| Pts. With prior Surgery (notspec.)     |       |   |     |                     |
| Parity: Parous                         |       |   |     |                     |
| Mean Parity                            |       |   |     |                     |
| Min Parity                             |       |   |     |                     |
| Max Parity                             |       |   |     |                     |
| Mean Deliveries/Pt.                    |       |   |     |                     |
| Nulliparous                            |       |   |     |                     |

**Stress Urinary Incontinence****Group Characteristics****10. Other Patient Characteristics (cont.)**

|                 | Check | % | Num | Comments/Definition |
|-----------------|-------|---|-----|---------------------|
| Obesity         |       |   |     |                     |
| Pre-Menopausal  |       |   |     |                     |
| With Estrogen   |       |   |     |                     |
| Post-Menopausal |       |   |     |                     |
| With Estrogen   |       |   |     |                     |

**11. Methods of Evaluation**

| <b>Subjective</b> | Check | % | Num | Comments/Definition |
|-------------------|-------|---|-----|---------------------|
| Pt. Interview     |       |   |     |                     |
| Voiding Diary/Log |       |   |     |                     |
| MD Perception     |       |   |     |                     |
| Chart Review      |       |   |     |                     |
| Rating Form       |       |   |     |                     |
| QOL Rating        |       |   |     |                     |
| Analog Scale      |       |   |     |                     |
| Questionnaire     |       |   |     |                     |
| Other             |       |   |     |                     |
| Unspecified       |       |   |     |                     |

| <b>Objective</b>  | Check | % | Num | Comments/Definition |
|-------------------|-------|---|-----|---------------------|
| Physical Exam     |       |   |     |                     |
| Stress Test       |       |   |     |                     |
| BN Evaluation     |       |   |     |                     |
| Q-tip             |       |   |     |                     |
| Pad Test          |       |   |     |                     |
| Pads/Diapers      |       |   |     |                     |
| Baden-Walker      |       |   |     |                     |
| POP-Q             |       |   |     |                     |
| VCUG              |       |   |     |                     |
| Urodynamics       |       |   |     |                     |
| Video-Urodynamics |       |   |     |                     |
| Barrier Testing   |       |   |     |                     |
| Other             |       |   |     |                     |



American Urological Association, Inc.

Reference # \_\_\_\_\_

SUI Guidelines Panel

Group Number: \_\_\_\_\_

**Stress Urinary Incontinence****Group Characteristics**12. Diagnostic Findings ☐ Symptoms only ☐ Stress test ☐ Urodynamics

|     | Check | % | Num | Comments/Definition |
|-----|-------|---|-----|---------------------|
| SUI |       |   |     |                     |
| ISD |       |   |     |                     |

|     |  |  |  |  |
|-----|--|--|--|--|
| SUI |  |  |  |  |
| ISD |  |  |  |  |

| Grade  | Check | % | Num | Comments/Definition |
|--------|-------|---|-----|---------------------|
| Mild   |       |   |     |                     |
| Mod    |       |   |     |                     |
| Severe |       |   |     |                     |

|        |  |  |  |  |
|--------|--|--|--|--|
| Mild   |  |  |  |  |
| Mod    |  |  |  |  |
| Severe |  |  |  |  |

|         | Mean | Median | Min | Max | Check | % | Num | Comments/Definition |
|---------|------|--------|-----|-----|-------|---|-----|---------------------|
| Pads    |      |        |     |     |       |   |     |                     |
| Diapers |      |        |     |     |       |   |     |                     |

|         |  |  |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|--|
| Pads    |  |  |  |  |  |  |  |  |
| Diapers |  |  |  |  |  |  |  |  |

|                                 | Check | % | Num | Comments/Definition |
|---------------------------------|-------|---|-----|---------------------|
| Urodynamically proven motor DO  |       |   |     |                     |
| Urgency symptoms                |       |   |     |                     |
| Mixed (SUI/motor DO or Urgency) |       |   |     |                     |

|                                 |  |  |  |  |
|---------------------------------|--|--|--|--|
| Urodynamically proven motor DO  |  |  |  |  |
| Urgency symptoms                |  |  |  |  |
| Mixed (SUI/motor DO or Urgency) |  |  |  |  |

13. Comments on Group Characteristics

## SUI Guidelines Panel

## Stress Urinary Incontinence

## Treatments

## 14. Treatments

SUI handled before or after Prolapse repair or sling: before / after (circle one)

A. Treatments for Incontinence  
Suspensions

|   | Check | % | Num | Comments/Definition |
|---|-------|---|-----|---------------------|
| Open Retropubic Suspensions               |       |   |     |                     |
| Laparoscopic Suspension                   |       |   |     |                     |
| Transvaginal Cooper's Ligament Suspension |       |   |     |                     |
| Burch Suspension                          |       |   |     |                     |
| Other Suspensions (specify)               |       |   |     |                     |

## Slings

|  | Check | % | Num | Comments/Definition |
|--|-------|---|-----|---------------------|
| Autologous fascia w/o bone anchors               |       |   |     |                     |
| Autologous fascia with bone anchors              |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Autologous vaginal wall slings w/o bone anchors  |       |   |     |                     |
| Autologous vaginal wall slings with bone anchors |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Cadaveric w/o bone anchors                       |       |   |     |                     |
| Cadaveric with bone anchors                      |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Xenograft w/o bone anchors                       |       |   |     |                     |
| Xenograft with bone anchors                      |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Synthetic at bladder neck w/o bone anchors       |       |   |     |                     |
| Synthetic at bladder neck with bone anchors      |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Synthetic at midurethra                          |       |   |     |                     |
| Homologous tissue (dermis) w/o bone anchors      |       |   |     |                     |
| Homologous tissue (dermis) with bone anchors     |       |   |     |                     |
| transvaginal                                     |       |   |     |                     |
| suprapubic                                       |       |   |     |                     |
| Cooper's ligament sling (all sling materials)    |       |   |     |                     |
| Other Sling (specify)                            |       |   |     |                     |

Check % Num Comments/Definition

## Artificial Sphincter

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  |  |  |
|--|--|--|--|--|

## Injectables

|                                 | Check | % | Num | Comments/Definition |
|---------------------------------|-------|---|-----|---------------------|
| Collagen                        |       |   |     |                     |
| Other degradable materials      |       |   |     |                     |
| Other non-degradable synthetics |       |   |     |                     |
| Other Injectables (specify)     |       |   |     |                     |

**Stress Urinary Incontinence****Treatments****14B. Treatments for Prolapse****Anterior compartment repairs**

|                          | Check | % | Num | Comments/Definition |
|--------------------------|-------|---|-----|---------------------|
| Plication (colporrhaphy) |       |   |     |                     |
| Paravaginal              |       |   |     |                     |
| Abdominal approach       |       |   |     |                     |
| Vaginal approach         |       |   |     |                     |
| Interposition graft      |       |   |     |                     |
| Combination (specify)    |       |   |     |                     |
| Other (specify)          |       |   |     |                     |
| Not Stated               |       |   |     |                     |

**Apical Repair**

|                                    | Check | % | Num | Comments/Definition |
|------------------------------------|-------|---|-----|---------------------|
| McCall Procedure                   |       |   |     |                     |
| Uterosacral Suspension (plication) |       |   |     |                     |
| Levator myorrhaphy                 |       |   |     |                     |
| Iliococcygeus repair               |       |   |     |                     |
| Sacrocolpopexy                     |       |   |     |                     |
| Sacrospinous fixation              |       |   |     |                     |
| Other (specify)                    |       |   |     |                     |
| Not Stated                         |       |   |     |                     |

**Posterior Compartment Repairs**

|                     | Check | % | Num | Comments/Definition |
|---------------------|-------|---|-----|---------------------|
| Site specific       |       |   |     |                     |
| Plication           |       |   |     |                     |
| Interposition graft |       |   |     |                     |
| Combination repair  |       |   |     |                     |
| Other (specify)     |       |   |     |                     |
| Not Stated          |       |   |     |                     |

**Enterocoele repair**

|                            | Check | % | Num | Comments/Definition |
|----------------------------|-------|---|-----|---------------------|
| Culdoplasty (specify)      |       |   |     |                     |
| Plication                  |       |   |     |                     |
| Other, Transvaginal Repair |       |   |     |                     |
| Other, Abdominal Repair    |       |   |     |                     |

**C. Other Treatments**

|                        | Check | % | Num | Comments/Definition |
|------------------------|-------|---|-----|---------------------|
| Abdominal hysterectomy |       |   |     |                     |
| Vaginal hysterectomy   |       |   |     |                     |
|                        |       |   |     |                     |
|                        |       |   |     |                     |
|                        |       |   |     |                     |
|                        |       |   |     |                     |

**15. Comments about treatments for this group:**

**Stress Urinary Incontinence****Group Outcomes**

16. Patients w. Follow-up: N= \_\_\_\_\_ Mean: \_\_\_\_\_ Median: \_\_\_\_\_ Min: \_\_\_\_\_ Max: \_\_\_\_\_  
 Follow-up (mo): \_\_\_\_\_

**17. Outcome Assessment Tools:**

| Subjective        | Check | % | Num | Comments/Definition of Success/Failure |
|-------------------|-------|---|-----|--|
| Pt. Interview     |       |   |     |  |
| Voiding Diary/Log |       |   |     |  |
| MD Perception     |       |   |     |  |
| Chart Review      |       |   |     |  |
| Rating Form       |       |   |     |  |
| QOL Rating        |       |   |     |  |
| Analog Scale      |       |   |     |  |
| Questionnaire     |       |   |     |  |
| Other             |       |   |     |  |
| Unspecified       |       |   |     |  |

| Objective         | Check | % | Num | Comments/ Definition of Success/Failure |
|-------------------|-------|---|-----|---|
| Physical Exam     |       |   |     |   |
| Stress Test       |       |   |     |   |
| BN Evaluation     |       |   |     |   |
| Q-tip             |       |   |     |   |
| Pad Test          |       |   |     |   |
| Pads/Diapers      |       |   |     |   |
| Baden-Walker      |       |   |     |   |
| POP-Q             |       |   |     |   |
| VCUG              |       |   |     |   |
| Urodynamics       |       |   |     |   |
| Video-Urodynamics |       |   |     |   |
| Barrier Testing   |       |   |     |   |
| Other             |       |   |     |   |

**18. Outcomes in Regard to Continence Status only**

| 1 <sup>st</sup>                | Subj | Obj         | % | Num | Denom | Comments\Definition |
|--------------------------------|------|-------------|---|-----|-------|---------------------|
| _____ Months                   |      | Cure/Dry    |   |     |       |                     |
| _____ Mean Mos                 |      | Improved    |   |     |       |                     |
| _____ Median Mos               |      | Failure     |   |     |       |                     |
| _____ Min Mos                  |      | Retreatment |   |     |       |                     |
| _____ Max Mos                  |      |             |   |     |       |                     |
| _____ SE Mos                   |      |             |   |     |       |                     |
| _____ STDev Mos                |      |             |   |     |       |                     |
| _____ % CI, _____ to _____ Mos |      |             |   |     |       |                     |

**Stress Urinary Incontinence****Group Outcomes****18. Outcomes in Regard to Continence Status only (cont.)**

| 2 <sup>nd</sup>          | ___ Subj | ___ Obj     | % | Num | Denom | Comments\Definition |
|--------------------------|----------|-------------|---|-----|-------|---------------------|
| ___ Months               |          | Cure/Dry    |   |     |       |                     |
| ___ Mean Mos             |          | Improved    |   |     |       |                     |
| ___ Median Mos           |          | Failure     |   |     |       |                     |
| ___ Min Mos              |          | Retreatment |   |     |       |                     |
| ___ Max Mos              |          |             |   |     |       |                     |
| ___ SE Mos               |          |             |   |     |       |                     |
| ___ STDev Mos            |          |             |   |     |       |                     |
| ___ % CI, ___ to ___ Mos |          |             |   |     |       |                     |

| 3 <sup>rd</sup>          | ___ Subj | ___ Obj     | % | Num | Denom | Comments\Definition |
|--------------------------|----------|-------------|---|-----|-------|---------------------|
| ___ Months               |          | Cure/Dry    |   |     |       |                     |
| ___ Mean Mos             |          | Improved    |   |     |       |                     |
| ___ Median Mos           |          | Failure     |   |     |       |                     |
| ___ Min Mos              |          | Retreatment |   |     |       |                     |
| ___ Max Mos              |          |             |   |     |       |                     |
| ___ SE Mos               |          |             |   |     |       |                     |
| ___ STDev Mos            |          |             |   |     |       |                     |
| ___ % CI, ___ to ___ Mos |          |             |   |     |       |                     |

**19. Management of Bladder:**

| Method of Bladder Drainage | Check | % | Num | Denom | Comments\Definition |
|----------------------------|-------|---|-----|-------|---------------------|
| Foley Catheter             |       |   |     |       |                     |
| Suprapubic Catheter        |       |   |     |       |                     |
| Self Catheterization       |       |   |     |       |                     |

Author's Definition of Retention: \_\_\_\_\_

| Patients in Retention | @Days | % | Num | Denom | Comments\Definition |
|-----------------------|-------|---|-----|-------|---------------------|
| ___ @ Discharge       |       |   |     |       |                     |
|                       |       |   |     |       |                     |
|                       |       |   |     |       |                     |
|                       |       |   |     |       |                     |

| Days in Retention | Mean | Median | Min | Max | SE | STDev |  | %CI |
|-------------------|------|--------|-----|-----|----|-------|--|-----|
|                   |      |        |     |     |    |       |  |     |

| Secondary Procedures for Patients in Retention | @ Mo | Num | Prev. |
|--|------|-----|-------|
| 1.   |      |     |       |
| 2.   |      |     |       |
| 3.   |      |     |       |
| 4.   |      |     |       |

**Stress Urinary Incontinence****Group Outcomes****20. Complications (Peri-operative and during Follow-Up)**

|                             | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------------|------|-------|---|-----|-------|---------------------|
| None (per Author)           |      |       |   |     |       |                     |
| Transfusion                 |      |       |   |     |       |                     |
| Acute Bleeding              |      |       |   |     |       |                     |
| Hematoma                    |      |       |   |     |       |                     |
| Death                       |      |       |   |     |       |                     |
| Infection                   |      |       |   |     |       |                     |
| Local Extension             |      |       |   |     |       |                     |
| Systemic                    |      |       |   |     |       |                     |
| Wound                       |      |       |   |     |       |                     |
| UTI                         |      |       |   |     |       |                     |
| Wound                       |      |       |   |     |       |                     |
| Vaginal                     |      |       |   |     |       |                     |
| Major                       |      |       |   |     |       |                     |
| Minor                       |      |       |   |     |       |                     |
| Abdominal                   |      |       |   |     |       |                     |
| Major                       |      |       |   |     |       |                     |
| Minor                       |      |       |   |     |       |                     |
| Removal of For. Body- other |      |       |   |     |       |                     |
| Stitches                    |      |       |   |     |       |                     |
| Pledget                     |      |       |   |     |       |                     |
| PE/DVT                      |      |       |   |     |       |                     |
| MI                          |      |       |   |     |       |                     |
| CVA                         |      |       |   |     |       |                     |
| Pulmonary                   |      |       |   |     |       |                     |
| Bladder Injury              |      |       |   |     |       |                     |
| Bowel Injury                |      |       |   |     |       |                     |
| Vascular Injury             |      |       |   |     |       |                     |
| Rectal Injury               |      |       |   |     |       |                     |
| Fistula                     |      |       |   |     |       |                     |
| Dysuria                     |      |       |   |     |       |                     |
| Sexual Dysfunction          |      |       |   |     |       |                     |
| Urethral Erosion            |      |       |   |     |       |                     |
| Other Complications         |      |       |   |     |       |                     |
| Other Complications         |      |       |   |     |       |                     |
| Other Complications         |      |       |   |     |       |                     |
| Other Complications         |      |       |   |     |       |                     |

**21. Bleeding**

Mean: \_\_\_\_\_ Median: \_\_\_\_\_ Min: \_\_\_\_\_ Max: \_\_\_\_\_

**Stress Urinary Incontinence****Group Outcomes****22. Urgency and Urge Incontinence**

|                               | Time | Check | % | Num | Denom | Comments\Definition |
|-------------------------------|------|-------|---|-----|-------|---------------------|
| Urge Incontinence – New onset |      |       |   |     |       |                     |
| Pre-existing                  |      |       |   |     |       |                     |
| Unspecified                   |      |       |   |     |       |                     |
| Urgency symptoms – New onset  |      |       |   |     |       |                     |
| Pre-existing                  |      |       |   |     |       |                     |
| Unspecified                   |      |       |   |     |       |                     |
| Unspecified urgency–New onset |      |       |   |     |       |                     |
| Pre-existing                  |      |       |   |     |       |                     |
| Unspecified                   |      |       |   |     |       |                     |

**23. Prolapse Outcomes****A. Cystocele**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

**B. Rectocele**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

**C. Enterocele**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

**D. Uterine Prolapse**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

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**Stress Urinary Incontinence****Group Outcomes****E. Vault Prolapse**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

**F. Other/unspecified/total ( \_\_\_\_\_ )**

|                       | Time | Check | % | Num | Denom | Comments\Definition |
|-----------------------|------|-------|---|-----|-------|---------------------|
| Recurrence            |      |       |   |     |       |                     |
| Failure               |      |       |   |     |       |                     |
| New Prolapse          |      |       |   |     |       |                     |
| Post-op (unspecified) |      |       |   |     |       |                     |
| Other (specify)       |      |       |   |     |       |                     |

**24. Comments** (regarding this group only)



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7109 articles listed

SUI Guideline Update Panel

Efficacy - Cure / Dry  
ANY Prolapse\*

|   | SUBJECTIVE Eval |        |                  | OBJECTIVE Eval |        |                  | ANY Eval       |        |                  |
|---|-----------------|--------|------------------|----------------|--------|------------------|----------------|--------|------------------|
|   | 12 - 23 months  |        |                  | 12 - 23 months |        |                  | 12 - 23 months |        |                  |
|   | G/P             | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% |
| <b>Suspensions</b>  |                 |        |                  |                |        |                  |                |        |                  |
| All Open Retropubic   | 7/460           | 89%    | (84 - 93)%       | 2/35           | 86%    | (69 - 96)%       | 9/517          | 88%    | (83 - 92)%       |
| Burch   | 7/460           | 89%    | (84 - 93)%       | 2/35           | 86%    | (69 - 96)%       | 9/517          | 88%    | (83 - 92)%       |
| Laparoscopic  | 3/150           | 87%    | (75 - 94)%       | 4/146          | 87%    | (81 - 92)%       | 12/564         | 88%    | (85 - 91)%       |
| <b>Slings</b>   |                 |        |                  |                |        |                  |                |        |                  |
| Autologous fascia without bone anchors                        | 1/36            | 89%    | (76 - 96)%       | 2/42           | 97%    | (87 - 100)%      | 3/78           | 92%    | (82 - 97)%       |
| Autologous vaginal wall slings w/without bone anchors         |                 |        |                  |                |        |                  | 1/20           | 70%    | (48 - 86)%       |
| Autologous vaginal wall slings with bone anchors - Suprapubic |                 |        |                  |                |        |                  | 1/19           | 99%    | (88 - 100)%      |
| Cadaveric with bone anchors - Transvaginal                    | 1/234           | 82%    | (77 - 86)%       |                |        |                  | 1/234          | 82%    | (77 - 86)%       |
| Cadaveric without bone anchors                                | 3/133           | 58%    | (36 - 78)%       |                |        |                  | 3/133          | 58%    | (36 - 78)%       |
| Homologous tissue (dermis) without bone anchors               |                 |        |                  |                |        |                  |                |        |                  |
| Synthetic at bladder neck with bone anchors - Suprapubic      |                 |        |                  |                |        |                  |                |        |                  |
| Synthetic at bladder neck with bone anchors - Transvaginal    |                 |        |                  |                |        |                  |                |        |                  |
| Synthetic at bladder neck without bone anchors                |                 |        |                  |                |        |                  | 1/20           | 94%    | (79 - 99)%       |
| Synthetic at midurethra                                       | 8/647           | 85%    | (80 - 89)%       | 8/489          | 86%    | (77 - 93)%       | 14/1089        | 85%    | (80 - 89)%       |
| Other Sling   |                 |        |                  |                |        |                  | 1/126          | 92%    | (86 - 96)%       |
| <b>Injectables</b>  |                 |        |                  |                |        |                  |                |        |                  |
| Other non-degradable synthetics                               |                 |        |                  |                |        |                  |                |        |                  |
| <b>Artificial Sphincter</b>                                   |                 |        |                  |                |        |                  |                |        |                  |

Note: **G/P:** **G** = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment

SUI Guideline Update Panel

Efficacy - Cure / Dry  
ANY Prolapse\*

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

**SUBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 7/346 | 83%    | (75 - 90)%       |
| 6/306 | 83%    | (73 - 91)%       |
| 2/186 | 86%    | (59 - 98)%       |

**OBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 3/98  | 78%    | (55 - 93)%       |
| 2/58  | 87%    | (59 - 99)%       |
| 2/201 | 91%    | (85 - 96)%       |

**ANY Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 9/403 | 83%    | (75 - 90)%       |
| 7/333 | 85%    | (75 - 93)%       |
| 7/359 | 83%    | (73 - 91)%       |

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Autologous vaginal wall slings with bone anchors - Suprapubic  
Cadaveric with bone anchors - Transvaginal  
Cadaveric without bone anchors  
Homologous tissue (dermis) without bone anchors  
Synthetic at bladder neck with bone anchors - Suprapubic  
Synthetic at bladder neck with bone anchors - Transvaginal  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra  
Other Sling

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/80  | 85%    | (76 - 92)%       |
| 2/60  | 89%    | (64 - 99)%       |
|       |        |                  |
|       |        |                  |
| 1/39  | 39%    | (24 - 54)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/98  | 76%    | (66 - 83)%       |
| 6/543 | 83%    | (74 - 91)%       |
|       |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
|       |        |                  |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/19  | 89%    | (70 - 98)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/62  | 61%    | (49 - 73)%       |
| 4/446 | 92%    | (88 - 95)%       |
|       |        |                  |

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 1/80   | 85%    | (76 - 92)%       |
| 2/60   | 89%    | (64 - 99)%       |
| 1/9    | 87%    | (59 - 99)%       |
|        |        |                  |
| 2/92   | 64%    | (21 - 95)%       |
| 1/19   | 89%    | (70 - 98)%       |
|        |        |                  |
| 1/32   | 81%    | (65 - 92)%       |
| 3/184  | 75%    | (56 - 90)%       |
| 11/881 | 87%    | (81 - 91)%       |
|        |        |                  |

**Injectables**

Other non-degradable synthetics

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

**Artificial Sphincter**

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/206 | 81%    | (75 - 86)%       |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/206 | 81%    | (75 - 86)%       |

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Efficacy - Cure / Dry  
ANY Prolapse\*

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

**SUBJECTIVE Eval**

48 months and greater

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 7/541 | 75%    | (61 - 87)%       |
| 6/423 | 71%    | (55 - 85)%       |
|       |        |                  |

**OBJECTIVE Eval**

48 months and greater

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 1/56 | 80%    | (69 - 89)%       |
| 1/56 | 80%    | (69 - 89)%       |
|      |        |                  |

**ANY Eval**

48 months and greater

| G/P     | Median | CI (2.5 - 97.5)% |
|---------|--------|------------------|
| 13/1072 | 67%    | (56 - 76)%       |
| 12/954  | 65%    | (53 - 74)%       |
| 1/34    | 88%    | (74 - 96)%       |

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Autologous vaginal wall slings with bone anchors - Suprapubic  
Cadaveric with bone anchors - Transvaginal  
Cadaveric without bone anchors  
Homologous tissue (dermis) without bone anchors  
Synthetic at bladder neck with bone anchors - Suprapubic  
Synthetic at bladder neck with bone anchors - Transvaginal  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra  
Other Sling

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
|      |        |                  |
|      |        |                  |
|      |        |                  |
| 1/13 | 31%    | (11 - 58)%       |
|      |        |                  |
|      |        |                  |
|      |        |                  |
| 1/90 | 82%    | (73 - 89)%       |
|      |        |                  |
|      |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
|       |        |                  |
| 1/82  | 95%    | (89 - 98)%       |
|       |        |                  |
| 1/13  | 31%    | (11 - 58)%       |
|       |        |                  |
| 1/49  | 85%    | (74 - 93)%       |
|       |        |                  |
| 3/182 | 73%    | (62 - 82)%       |
| 2/101 | 76%    | (64 - 85)%       |
|       |        |                  |

**Injectables**

Other non-degradable synthetics

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 1/16 | 32%    | (13 - 56)%       |

**Artificial Sphincter**

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved

ANY Prolapse\*

SUBJECTIVE Eval

12 - 23 months

OBJECTIVE Eval

12 - 23 months

ANY Eval

12 - 23 months

| Suspensions   | G/P   | Median | CI (2.5 - 97.5)% | G/P   | Median | CI (2.5 - 97.5)% | G/P     | Median | CI (2.5 - 97.5)% |
|---|-------|--------|------------------|-------|--------|------------------|---------|--------|------------------|
| All Open Retropubic   | 8/638 | 89%    | (86 - 92)%       | 4/189 | 92%    | (86 - 97)%       | 12/849  | 90%    | (86 - 97)%       |
| Burch   | 8/638 | 89%    | (86 - 92)%       | 4/189 | 92%    | (86 - 97)%       | 12/849  | 90%    | (87 - 92)%       |
| Laparoscopic  | 3/150 | 88%    | (79 - 94)%       | 6/224 | 85%    | (78 - 91)%       | 14/642  | 88%    | (85 - 91)%       |
| Slings  | G/P   | Median | CI (2.5 - 97.5)% | G/P   | Median | CI (2.5 - 97.5)% | G/P     | Median | CI (2.5 - 97.5)% |
| Autologous fascia without bone anchors                        | 1/36  | 89%    | (76 - 96)%       | 2/42  | 97%    | (87 - 100)%      | 3/78    | 92%    | (82 - 97)%       |
| Autologous vaginal wall slings w/without bone anchors         |       |        |                  |       |        |                  | 1/20    | 99%    | (88 - 100)%      |
| Autologous vaginal wall slings with bone anchors - Suprapubic |       |        |                  |       |        |                  | 1/19    | 99%    | (88 - 100)%      |
| Cadaveric with bone anchors - Transvaginal                    | 1/234 | 82%    | (77 - 86)%       |       |        |                  | 1/234   | 82%    | (77 - 86)%       |
| Cadaveric without bone anchors                                | 3/133 | 81%    | (69 - 90)%       |       |        |                  | 3/133   | 81%    | (69 - 90)%       |
| Homologous tissue (dermis) without bone anchors               |       |        |                  |       |        |                  |         |        |                  |
| Synthetic at bladder neck with bone anchors - Suprapubic      |       |        |                  |       |        |                  |         |        |                  |
| Synthetic at bladder neck with bone anchors - Transvaginal    |       |        |                  |       |        |                  |         |        |                  |
| Synthetic at bladder neck without bone anchors                |       |        |                  |       |        |                  | 1/20    | 99%    | (88 - 100)%      |
| Synthetic at midurethra                                       | 9/688 | 92%    | (88 - 95)%       | 8/460 | 89%    | (81 - 94)%       | 15/1121 | 93%    | (89 - 95)%       |
| Other Sling   |       |        |                  |       |        |                  | 1/126   | 94%    | (89 - 97)%       |
| Injectables   | G/P   | Median | CI (2.5 - 97.5)% | G/P   | Median | CI (2.5 - 97.5)% | G/P     | Median | CI (2.5 - 97.5)% |
| Other non-degradable synthetics                               |       |        |                  |       |        |                  |         |        |                  |
| Artificial Sphincter  | G/P   | Median | CI (2.5 - 97.5)% | G/P   | Median | CI (2.5 - 97.5)% | G/P     | Median | CI (2.5 - 97.5)% |
|   |       |        |                  |       |        |                  |         |        |                  |

Note: **G/P**: **G** = Number of **G**roups/Treatment arms extracted / **P** = Number of **P**atients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.



SUI Guideline Update Panel

**Efficacy - Cure / Dry / Improved  
 ANY Prolapse\***

**SUBJECTIVE Eval**  
 24 - 47 months

**OBJECTIVE Eval**  
 24 - 47 months

**ANY Eval**  
 24 - 47 months

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 7/346 | 93%    | (87 - 97)%       |
| 6/306 | 92%    | (85 - 97)%       |
| 3/199 | 89%    | (77 - 96)%       |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 4/174 | 83%    | (69 - 93)%       |
| 3/134 | 89%    | (77 - 96)%       |
| 2/201 | 95%    | (90 - 99)%       |

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 10/459 | 91%    | (85 - 95)%       |
| 8/389  | 92%    | (87 - 96)%       |
| 8/372  | 89%    | (84 - 92)%       |

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors - Suprapubic  
 Cadaveric with bone anchors - Transvaginal  
 Cadaveric without bone anchors  
 Homologous tissue (dermis) without bone anchors  
 Synthetic at bladder neck with bone anchors - Suprapubic  
 Synthetic at bladder neck with bone anchors - Transvaginal  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra  
 Other Sling

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/80  | 95%    | (89 - 98)%       |
| 2/60  | 93%    | (81 - 99)%       |
|       |        |                  |
|       |        |                  |
| 1/39  | 39%    | (24 - 54)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/98  | 76%    | (66 - 83)%       |
| 6/543 | 91%    | (86 - 95)%       |
|       |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
|       |        |                  |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/19  | 94%    | (78 - 99)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/62  | 61%    | (49 - 73)%       |
| 4/446 | 95%    | (89 - 99)%       |
|       |        |                  |

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 1/80   | 95%    | (89 - 98)%       |
| 2/60   | 93%    | (81 - 99)%       |
| 1/9    | 87%    | (59 - 99)%       |
|        |        |                  |
| 2/92   | 64%    | (21 - 95)%       |
| 1/19   | 94%    | (78 - 99)%       |
|        |        |                  |
| 1/32   | 87%    | (73 - 96)%       |
| 3/184  | 75%    | (56 - 90)%       |
| 10/769 | 92%    | (88 - 95)%       |
|        |        |                  |

**Injectables**

Other non-degradable synthetics

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

**Artificial Sphincter**

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/206 | 88%    | (83 - 92)%       |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/206 | 88%    | (83 - 92)%       |

Note: **G/P:** **G** = Number of **G**roups/Treatment arms extracted / **P** = Number of **P**atients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

**Efficacy - Cure / Dry / Improved  
 ANY Prolapse\***

**SUBJECTIVE Eval**  
 48 months and greater

**OBJECTIVE Eval**  
 48 months and greater

**ANY Eval**  
 48 months and greater

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 8/557 | 80%    | (70 - 87)%       |
| 7/439 | 77%    | (66 - 86)%       |
|       |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 3/110 | 80%    | (70 - 88)%       |
| 3/100 | 80%    | (70 - 88)%       |
|       |        |                  |

| G/P     | Median | CI (2.5 - 97.5)% |
|---------|--------|------------------|
| 15/1118 | 78%    | (71 - 83)%       |
| 14/1000 | 76%    | (69 - 82)%       |
| 1/34    | 88%    | (74 - 96)%       |

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors - Suprapubic  
 Cadaveric with bone anchors - Transvaginal  
 Cadaveric without bone anchors  
 Homologous tissue (dermis) without bone anchors  
 Synthetic at bladder neck with bone anchors - Suprapubic  
 Synthetic at bladder neck with bone anchors - Transvaginal  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra  
 Other Sling

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/198 | 70%    | (63 - 76)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/13  | 61%    | (35 - 84)%       |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 1/90  | 82%    | (73 - 89)%       |
|       |        |                  |
|       |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |
|     |        |                  |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 1/198 | 70%    | (63 - 76)%       |
| 1/82  | 95%    | (89 - 98)%       |
|       |        |                  |
|       |        |                  |
| 1/13  | 61%    | (35 - 84)%       |
|       |        |                  |
| 1/49  | 90%    | (79 - 96)%       |
|       |        |                  |
| 3/182 | 73%    | (62 - 82)%       |
| 2/101 | 81%    | (70 - 90)%       |
|       |        |                  |

**Injectables**

Other non-degradable synthetics

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 1/16 | 56%    | (33 - 78)%       |

**Artificial Sphincter**

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

Note: **G/P:** **G** = Number of **G**roups/Treatment arms extracted / **P** = Number of **P**atients in those groups

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SUI Guideline Update Panel

Retention  
ANY Prolapse\*

> 28 days or Intervention

| Suspensions         | G/P    | Median | CI (2.5 - 97.5)% |
|---------------------|--------|--------|------------------|
| All Open Retropubic | 13/851 | 1%     | (1 - 3)%         |
| Burch               | 10/710 | 1%     | (1 - 3)%         |
| Laparoscopic        | 11/482 | 2%     | (1 - 4)%         |

| Slings  | G/P     | Median | CI (2.5 - 97.5)% |
|---|---------|--------|------------------|
| Autologous fascia without bone anchors                        | 3/301   | 5%     | (2 - 11)%        |
| Autologous vaginal wall slings w/without bone anchors         | 3/142   | 5%     | (1 - 17)%        |
| Autologous vaginal wall slings with bone anchors - Suprapubic | 1/25    | 1%     | (0 - 9)%         |
| Cadaveric without bone anchors                                | 1/26    | 1%     | (0 - 10)%        |
| Synthetic at bladder neck with bone anchors - Suprapubic      | 1/49    | 4%     | (1 - 12)%        |
| Synthetic at bladder neck with bone anchors - Transvaginal    | 2/99    | 1%     | (0 - 6)%         |
| Synthetic at bladder neck without bone anchors                | 7/422   | 10%    | (5 - 18)%        |
| Synthetic at midurethra                                       | 11/1107 | 3%     | (2 - 5)%         |

Note: **G/P:** **G** = Number of **G**roups/Treatment arms extracted / **P** = Number of **P**atients in those groups

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SUI Guideline Update Panel

Urgency  
ANY Prolapse\*

|                     |  |  | Urge Incontinence |        |                  |              |        |                  |             |        |                  |
|---------------------|--|--|-------------------|--------|------------------|--------------|--------|------------------|-------------|--------|------------------|
|                     |  |  | New Onset         |        |                  | Pre-Existing |        |                  | Unspecified |        |                  |
| Suspensions         |  |  | G/P               | Median | CI (2.5 - 97.5)% | G/P          | Median | CI (2.5 - 97.5)% | G/P         | Median | CI (2.5 - 97.5)% |
| All Open Retropubic |  |  | 10/457            | 14%    | (8 - 21)%        | 2/143        | 22%    | (4 - 56)%        | 2/256       | 13%    | (7 - 22)%        |
| Burch               |  |  | 9/417             | 14%    | (8 - 22)%        | 1/25         | 48%    | (30 - 67)%       | 2/256       | 13%    | (7 - 22)%        |
| Laparoscopic        |  |  | 5/344             | 11%    | (6 - 17)%        |              |        |                  | 1/32        | 4%     | (0 - 14)%        |

| Slings  |  |  |        |     |           |       |     |            |       |    |           |
|---|--|--|--------|-----|-----------|-------|-----|------------|-------|----|-----------|
| Autologous fascia without bone anchors                        |  |  | 2/97   | 10% | (4 - 19)% |       |     |            |       |    |           |
| Autologous vaginal wall slings w/without bone anchors         |  |  | 3/65   | 13% | (2 - 36)% | 2/15  | 47% | (21 - 75)% |       |    |           |
| Autologous vaginal wall slings with bone anchors - Suprapubic |  |  | 1/9    | 13% | (1 - 41)% |       |     |            |       |    |           |
| Cadaveric with bone anchors - Transvaginal                    |  |  | 1/238  | 6%  | (3 - 9)%  |       |     |            |       |    |           |
| Cadaveric without bone anchors                                |  |  |        |     |           |       |     |            |       |    |           |
| Homologous tissue (dermis) without bone anchors               |  |  | 1/5    | 22% | (2 - 63)% |       |     |            |       |    |           |
| Synthetic at bladder neck with bone anchors - Suprapubic      |  |  |        |     |           |       |     |            |       |    |           |
| Synthetic at bladder neck with bone anchors - Transvaginal    |  |  |        |     |           |       |     |            |       |    |           |
| Synthetic at bladder neck without bone anchors                |  |  | 4/150  | 15% | (5 - 31)% | 3/119 | 29% | (16 - 46)% |       |    |           |
| Synthetic at midurethra                                       |  |  | 11/805 | 11% | (7 - 16)% | 5/107 | 52% | (38 - 66)% | 2/174 | 9% | (1 - 38)% |
| Other Sling   |  |  |        |     |           |       |     |            |       |    |           |

Injectables

Artificial Sphincter

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**SUI Guideline Update Panel**

**Urgency  
ANY Prolapse\***

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

| Urgency Symptoms |        |                  |              |        |                  |             |        |                  |
|------------------|--------|------------------|--------------|--------|------------------|-------------|--------|------------------|
| New Onset        |        |                  | Pre-Existing |        |                  | Unspecified |        |                  |
| G/P              | Median | CI (2.5 - 97.5)% | G/P          | Median | CI (2.5 - 97.5)% | G/P         | Median | CI (2.5 - 97.5)% |
| 8/380            | 9%     | (6 - 13)%        | 2/23         | 40%    | (6 - 83)%        | 2/96        | 9%     | (4 - 18)%        |
| 8/380            | 9%     | (6 - 13)%        | 2/23         | 40%    | (6 - 83)%        | 2/96        | 9%     | (4 - 18)%        |
| 5/190            | 11%    | (4 - 21)%        | 1/2          | 10%    | (0 - 67)%        | 1/40        | 52%    | (37 - 67)%       |

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Autologous vaginal wall slings with bone anchors - Suprapubic  
Cadaveric with bone anchors - Transvaginal  
Cadaveric without bone anchors  
Homologous tissue (dermis) without bone anchors  
Synthetic at bladder neck with bone anchors - Suprapubic  
Synthetic at bladder neck with bone anchors - Transvaginal  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra  
Other Sling

|       |     |            |       |     |             |      |     |            |
|-------|-----|------------|-------|-----|-------------|------|-----|------------|
| 1/27  | 23% | (10 - 40)% |       |     |             |      |     |            |
| 1/45  | 1%  | (0 - 5)%   |       |     |             |      |     |            |
|       |     |            |       |     |             |      |     |            |
|       |     |            |       |     |             |      |     |            |
| 1/15  | 14% | (3 - 36)%  | 1/11  | 81% | (53 - 96)%  |      |     |            |
|       |     |            |       |     |             |      |     |            |
| 1/47  | 2%  | (0 - 10)%  | 1/2   | 90% | (33 - 100)% | 1/49 | 2%  | (0 - 10)%  |
| 1/32  | 7%  | (1 - 19)%  |       |     |             |      |     |            |
| 1/45  | 1%  | (0 - 5)%   |       |     |             | 1/47 | 2%  | (0 - 10)%  |
| 8/539 | 13% | (8 - 20)%  | 2/104 | 21% | (4 - 51)%   | 1/39 | 21% | (10 - 35)% |
| 1/126 | 21% | (14 - 29)% |       |     |             |      |     |            |

**Injectables**

**Artificial Sphincter**

Note: **G/P:** **G** = Number of **G**roups/Treatment arms extracted / **P** = Number of **P**atients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.



**SUI Guideline Update Panel**

**Urgency  
ANY Prolapse\***

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

| Unspecified Urgency |        |                  |              |        |                  |             |        |                  |
|---------------------|--------|------------------|--------------|--------|------------------|-------------|--------|------------------|
| New Onset           |        |                  | Pre-Existing |        |                  | Unspecified |        |                  |
| G/P                 | Median | CI (2.5 - 97.5)% | G/P          | Median | CI (2.5 - 97.5)% | G/P         | Median | CI (2.5 - 97.5)% |
| 2/85                | 16%    | (8 - 27)%        |              |        |                  |             |        |                  |
| 2/85                | 16%    | (8 - 27)%        |              |        |                  |             |        |                  |
| 2/73                | 12%    | (5 - 23)%        | 1/51         | 6%     | (2 - 15)%        | 1/30        | 24%    | (11 - 40)%       |

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Autologous vaginal wall slings with bone anchors - Suprapubic  
Cadaveric with bone anchors - Transvaginal  
Cadaveric without bone anchors  
Homologous tissue (dermis) without bone anchors  
Synthetic at bladder neck with bone anchors - Suprapubic  
Synthetic at bladder neck with bone anchors - Transvaginal  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra  
Other Sling

|      |    |           |      |     |            |       |     |           |
|------|----|-----------|------|-----|------------|-------|-----|-----------|
|      |    |           |      |     |            |       |     |           |
| 1/45 | 1% | (0 - 5)%  |      |     |            | 1/45  | 1%  | (0 - 5)%  |
|      |    |           |      |     |            |       |     |           |
|      |    |           |      |     |            |       |     |           |
|      |    |           |      |     |            | 1/36  | 17% | (7 - 31)% |
|      |    |           |      |     |            |       |     |           |
|      |    |           |      |     |            |       |     |           |
| 2/69 | 5% | (0 - 21)% |      |     |            |       |     |           |
| 1/16 | 1% | (0 - 14)% | 1/59 | 26% | (16 - 38)% | 2/214 | 7%  | (4 - 12)% |
|      |    |           |      |     |            |       |     |           |

**Injectables**

**Artificial Sphincter**

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**SUI Guideline Update Panel**  
**Complications**  
**ANY Prolapse\*\***

**Death**

**Transfusion**

**General Medical Complications**

Cardiovascular  
 Febrile  
 Infection  
 Infection/Local Extension  
 Neurologic  
 Pulmonary  
 Systemic - Abscess  
 UTI

**Operative Complications**

Bladder Injury  
 Bleeding  
 Bleeding - Acute  
 Bleeding - Hematoma  
 Bowel Injury  
 Erosion Extrusion  
 Erosion Extrusion - Unknown  
 Erosion Extrusion - Urethral-Bladder  
 Erosion Extrusion - Vaginal  
 Nerve Injury  
 Operative CX - Other  
 Osteomyelitis  
 Ureteral Injury  
 Urethral Injury  
 Urinary Tract Injury NS  
 Vaginal Operative CX  
 Wound  
 Abdominal  
 Vaginal

**Subjective Complications**

Pain  
 Sexual Dysfunction  
 Voiding Dysfunction

**Conversion**

**Other Complications**

**Suspensions**

| All Retropubic Suspensions |     |                  | Burch Suspension |     |                  | Laparoscopic Suspension |     |                  |
|----------------------------|-----|------------------|------------------|-----|------------------|-------------------------|-----|------------------|
| G/P                        | Med | CI (2.5 - 97.5)% | G/P              | Med | CI (2.5 - 97.5)% | G/P                     | Med | CI (2.5 - 97.5)% |
|                            |     |                  |                  |     |                  |                         |     |                  |

|       |    |           |       |    |           |       |    |          |
|-------|----|-----------|-------|----|-----------|-------|----|----------|
| 7/415 | 6% | (2 - 14)% | 6/375 | 7% | (2 - 16)% | 5/183 | 2% | (1 - 6)% |
|-------|----|-----------|-------|----|-----------|-------|----|----------|

|        |     |            |        |     |            |        |    |           |
|--------|-----|------------|--------|-----|------------|--------|----|-----------|
| 3/342  | 2%  | (1 - 4)%   | 3/342  | 2%  | (1 - 4)%   | 3/185  | 3% | (1 - 6)%  |
| 7/614  | 11% | (5 - 20)%  | 5/513  | 14% | (6 - 26)%  | 3/296  | 2% | (1 - 5)%  |
| 2/280  | 12% | (6 - 19)%  | 2/280  | 12% | (6 - 19)%  |        |    |           |
| 1/51   | 3%  | (1 - 7)%   | 1/51   | 3%  | (1 - 7)%   | 2/164  | 3% | (1 - 9)%  |
|        |     |            |        |     |            |        |    |           |
| 1/33   | 4%  | (0 - 13)%  |        |     |            | 2/151  | 3% | (1 - 7)%  |
| 1/82   | 4%  | (1 - 9)%   | 1/82   | 4%  | (1 - 9)%   | 2/149  | 3% | (1 - 8)%  |
| 10/779 | 17% | (11 - 25)% | 10/779 | 17% | (11 - 25)% | 11/545 | 7% | (5 - 11)% |

|       |     |            |       |    |           |        |    |           |
|-------|-----|------------|-------|----|-----------|--------|----|-----------|
| 8/503 | 3%  | (2 - 6)%   | 8/503 | 3% | (2 - 6)%  | 16/901 | 6% | (4 - 8)%  |
|       |     |            |       |    |           |        |    |           |
| 2/177 | 5%  | (1 - 13)%  | 2/177 | 5% | (1 - 13)% | 2/98   | 2% | (0 - 8)%  |
| 9/600 | 5%  | (3 - 7)%   | 8/560 | 5% | (3 - 7)%  | 7/366  | 3% | (2 - 6)%  |
| 2/150 | 2%  | (0 - 6)%   | 1/82  | 1% | (0 - 6)%  | 3/182  | 3% | (1 - 8)%  |
|       |     |            |       |    |           |        |    |           |
|       |     |            |       |    |           |        |    |           |
| 2/147 | 2%  | (0 - 5)%   | 2/147 | 2% | (0 - 5)%  | 4/201  | 6% | (2 - 11)% |
|       |     |            |       |    |           |        |    |           |
|       |     |            |       |    |           |        |    |           |
| 1/127 | 1%  | (0 - 4)%   | 1/127 | 1% | (0 - 4)%  | 1/36   | 1% | (0 - 7)%  |
| 2/2   | 71% | (23 - 98)% |       | *  |           |        |    |           |
|       | *   |            |       | *  |           | 3/109  | 4% | (1 - 10)% |
|       |     |            |       |    |           |        |    |           |
|       | *   |            |       | *  |           |        |    |           |
|       |     |            |       |    |           | 1/113  | 1% | (0 - 4)%  |
| 5/408 | 5%  | (3 - 9)%   | 5/408 | 5% | (3 - 9)%  | 4/206  | 4% | (1 - 8)%  |
| 3/233 | 5%  | (1 - 12)%  | 1/132 | 1% | (0 - 3)%  | 4/155  | 7% | (2 - 18)% |
|       |     |            |       |    |           | 1/48   | 0% | (0 - 5)%  |

|       |     |           |       |     |           |       |     |           |
|-------|-----|-----------|-------|-----|-----------|-------|-----|-----------|
| 2/76  | 9%  | (2 - 24)% | 2/76  | 9%  | (2 - 24)% | 7/353 | 3%  | (2 - 6)%  |
| 5/262 | 7%  | (4 - 12)% | 5/262 | 7%  | (4 - 12)% | 1/34  | 12% | (4 - 26)% |
| 3/314 | 16% | (5 - 33)% | 3/314 | 16% | (5 - 33)% | 3/104 | 8%  | (3 - 15)% |

|  |  |  |  |  |  |       |     |           |
|--|--|--|--|--|--|-------|-----|-----------|
|  |  |  |  |  |  | 3/219 | 11% | (5 - 20)% |
|--|--|--|--|--|--|-------|-----|-----------|

|       |    |           |       |    |           |      |    |           |
|-------|----|-----------|-------|----|-----------|------|----|-----------|
| 3/183 | 8% | (4 - 14)% | 3/183 | 8% | (4 - 14)% | 1/36 | 6% | (1 - 17)% |
|-------|----|-----------|-------|----|-----------|------|----|-----------|

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

# SUI Guideline Update Panel Complications ANY Prolapse\*\*

## Death

## Transfusion

## General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

## Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

## Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

## Conversion

## Other Complications

## Slings

| Autologous fascia    |     |                  | Autologous Vaginal Wall Slings |     |                  |                             |     |                  |
|----------------------|-----|------------------|--------------------------------|-----|------------------|-----------------------------|-----|------------------|
| without Bone Anchors |     |                  | with/without Bone anchors      |     |                  | w Bone Anchors - Suprapubic |     |                  |
| G/P                  | Med | CI (2.5 - 97.5)% | G/P                            | Med | CI (2.5 - 97.5)% | G/P                         | Med | CI (2.5 - 97.5)% |
|                      |     |                  |                                |     |                  |                             |     |                  |
| 1/198                | 4%  | (2 - 7)%         | 2/35                           | 9%  | (2 - 24)%        |                             |     |                  |

|      |     |           |      |     |           |  |  |  |
|------|-----|-----------|------|-----|-----------|--|--|--|
|      |     |           | 1/15 | 8%  | (1 - 27)% |  |  |  |
|      |     |           |      |     |           |  |  |  |
| 1/80 | 4%  | (1 - 10)% | 2/32 | 22% | (8 - 42)% |  |  |  |
|      |     |           |      |     |           |  |  |  |
|      |     |           |      |     |           |  |  |  |
| 1/80 | 10% | (5 - 18)% |      |     |           |  |  |  |
|      |     |           |      |     |           |  |  |  |
| 1/80 | 8%  | (3 - 15)% | 1/20 | 1%  | (0 - 12)% |  |  |  |

|       |    |           |      |    |           |  |   |  |
|-------|----|-----------|------|----|-----------|--|---|--|
| 2/278 | 8% | (1 - 26)% | 1/82 | 3% | (1 - 8)%  |  |   |  |
|       |    |           |      |    |           |  |   |  |
| 1/80  | 8% | (3 - 15)% | 1/20 | 6% | (1 - 21)% |  |   |  |
|       |    |           |      |    |           |  |   |  |
| 1/80  | 1% | (0 - 6)%  |      |    |           |  |   |  |
|       |    |           |      |    |           |  |   |  |
|       |    |           |      |    |           |  |   |  |
|       | *  |           | 1/20 | 1% | (0 - 12)% |  |   |  |
|       |    |           |      |    |           |  |   |  |
|       |    |           |      |    |           |  |   |  |
|       |    |           | 1/82 | 1% | (0 - 6)%  |  |   |  |
|       |    |           |      |    |           |  | * |  |
|       |    |           | 1/20 | 1% | (0 - 12)% |  |   |  |
|       |    |           |      |    |           |  |   |  |
|       |    |           |      |    |           |  |   |  |
| 2/278 | 4% | (2 - 8)%  |      |    |           |  |   |  |
|       |    |           | 1/82 | 3% | (1 - 8)%  |  | * |  |
|       |    |           | 2/65 | 3% | (0 - 11)% |  |   |  |

|      |    |          |      |    |           |  |  |  |
|------|----|----------|------|----|-----------|--|--|--|
| 1/80 | 3% | (1 - 8)% | 1/45 | 3% | (0 - 10)% |  |  |  |
|      |    |          |      |    |           |  |  |  |
|      |    |          |      |    |           |  |  |  |

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.



**SUI Guideline Update Panel  
 Complications  
 ANY Prolapse\*\***

**Slings**

**Synthetic at Bladder Neck**

**Death**

**Transfusion**

**General Medical Complications**

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

**Operative Complications**

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

**Subjective Complications**

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

**Conversion**

**Other Complications**

| Slings                    |     |                  |                             |     |                  |                      |     |                  |
|---------------------------|-----|------------------|-----------------------------|-----|------------------|----------------------|-----|------------------|
| Synthetic at Bladder Neck |     |                  |                             |     |                  |                      |     |                  |
| with Bone Anchors         |     |                  | w Bone Anchors - Suprapubic |     |                  | without Bone Anchors |     |                  |
| G/P                       | Med | CI (2.5 - 97.5)% | G/P                         | Med | CI (2.5 - 97.5)% | G/P                  | Med | CI (2.5 - 97.5)% |
|                           |     |                  |                             |     |                  |                      |     |                  |
|                           |     |                  |                             |     |                  | 2/92                 | 53% | (40 - 66)%       |

|  |  |  |      |    |          |       |     |            |
|--|--|--|------|----|----------|-------|-----|------------|
|  |  |  |      |    |          |       |     |            |
|  |  |  |      |    |          | 1/47  | 2%  | (0 - 10)%  |
|  |  |  | 1/49 | 0% | (0 - 5)% | 1/20  | 25% | (10 - 46)% |
|  |  |  |      |    |          |       |     |            |
|  |  |  |      |    |          |       |     |            |
|  |  |  |      |    |          |       |     |            |
|  |  |  |      |    |          |       |     |            |
|  |  |  |      |    |          | 3/112 | 9%  | (4 - 17)%  |

|  |   |  |      |    |          |       |     |            |
|--|---|--|------|----|----------|-------|-----|------------|
|  |   |  |      |    |          | 1/24  | 1%  | (0 - 10)%  |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          | 3/112 | 11% | (3 - 24)%  |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          | 2/143 | 12% | (2 - 36)%  |
|  |   |  | 1/49 | 2% | (0 - 9)% | 1/20  | 1%  | (0 - 12)%  |
|  |   |  | 1/49 | 0% | (0 - 5)% | 4/223 | 9%  | (5 - 19)%  |
|  | * |  |      |    |          |       |     |            |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          | 1/98  | 1%  | (0 - 12)%  |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          |       |     |            |
|  |   |  |      |    |          | 1/98  | 20% | (14 - 30)% |
|  |   |  |      |    |          | 1/98  | 40% | (31 - 50)% |
|  |   |  |      |    |          | 1/98  | 26% | (18 - 35)% |
|  |   |  |      |    |          | 1/20  | 1%  | (0 - 12)%  |

|  |  |      |    |           |       |     |           |
|--|--|------|----|-----------|-------|-----|-----------|
|  |  | 1/49 | 4% | (1 - 12)% | 1/62  | 2%  | (0 - 7)%  |
|  |  | 1/49 | 4% | (1 - 12)% |       |     |           |
|  |  | 1/49 | 0% | (0 - 5)%  | 2/122 | 16% | (3 - 38)% |

|  |  |  |  |  |  |  |  |
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|--|--|--|--|--|--|--|--|

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.



# SUI Guideline Update Panel

## Complications

### ANY Prolapse\*\*

#### Death

#### Transfusion

#### General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

#### Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

#### Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

#### Conversion

#### Other Complications

| Slings                  |     |                  |           |     |                  |             |     |                  |
|-------------------------|-----|------------------|-----------|-----|------------------|-------------|-----|------------------|
| Synthetic at Midurethra |     |                  | Xenograft |     |                  | Other Sling |     |                  |
| G/P                     | Med | CI (2.5 - 97.5)% | G/P       | Med | CI (2.5 - 97.5)% | G/P         | Med | CI (2.5 - 97.5)% |
| 9/3189                  | 1%  | (0 - 1)%         |           |     |                  | 1/126       | 0%  | (0 - 2)%         |

|         |    |           |      |     |            |       |    |          |
|---------|----|-----------|------|-----|------------|-------|----|----------|
| 2/2113  | 0% | (0 - 1)%  |      |     |            |       |    |          |
| 3/468   | 8% | (4 - 14)% |      |     |            |       |    |          |
| 1/1455  | 1% | (0 - 1)%  | 1/18 | 17% | (5 - 38)%  |       |    |          |
|         | *  |           |      |     |            |       |    |          |
| 1/75    | 2% | (0 - 6)%  |      |     |            |       |    |          |
|         |    |           |      |     |            |       |    |          |
| 2/111   | 3% | (1 - 9)%  | 1/10 | 60% | (30 - 85)% |       |    |          |
| 16/3016 | 7% | (5 - 9)%  |      |     |            | 1/126 | 1% | (0 - 4)% |

|         |    |          |      |     |           |       |    |           |
|---------|----|----------|------|-----|-----------|-------|----|-----------|
| 29/4248 | 6% | (5 - 8)% |      |     |           | 1/126 | 3% | (1 - 6)%  |
|         |    |          |      |     |           |       |    |           |
| 6/1921  | 2% | (1 - 3)% |      |     |           | 1/126 | 0% | (0 - 2)%  |
| 15/3770 | 3% | (2 - 4)% |      |     |           |       |    |           |
|         | *  |          |      |     |           |       |    |           |
|         |    |          |      |     |           |       |    |           |
| 6/632   | 4% | (2 - 7)% |      |     |           |       |    |           |
| 5/308   | 3% | (1 - 8)% |      |     |           |       |    |           |
| 6/2185  | 2% | (1 - 5)% |      |     |           |       |    |           |
| 3/1891  | 1% | (0 - 2)% |      |     |           |       |    |           |
|         |    |          |      |     |           |       |    |           |
|         |    |          |      |     |           |       |    |           |
|         |    |          |      |     |           |       |    |           |
| 5/1801  | 2% | (1 - 3)% |      |     |           | 1/126 | 0% | (0 - 2)%  |
|         |    |          |      |     |           |       |    |           |
| 3/393   | 1% | (0 - 3)% | 1/18 | 17% | (5 - 38)% | 1/126 | 5% | (2 - 10)% |
| 2/301   | 2% | (0 - 6)% |      |     |           |       |    |           |
| 3/1612  | 1% | (0 - 2)% |      |     |           |       |    |           |
| 1/45    | 1% | (0 - 5)% |      |     |           |       |    |           |

|        |     |           |  |  |  |  |  |  |
|--------|-----|-----------|--|--|--|--|--|--|
| 4/1985 | 3%  | (1 - 7)%  |  |  |  |  |  |  |
|        |     |           |  |  |  |  |  |  |
| 9/2407 | 16% | (6 - 33)% |  |  |  |  |  |  |

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|       |    |          |  |  |  |  |  |  |
|-------|----|----------|--|--|--|--|--|--|
| 1/193 | 1% | (0 - 2)% |  |  |  |  |  |  |
|-------|----|----------|--|--|--|--|--|--|

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group  
 \* Only case reports of this complication exist, and data are insufficient to estimate the frequency.  
 \*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**SUI Guideline Update Panel**  
**Complications**  
**ANY Prolapse\*\***

**Injectables**

| Collagen |     |                  | Artificial Sphincter |     |                  |
|----------|-----|------------------|----------------------|-----|------------------|
| G/P      | Med | CI (2.5 - 97.5)% | G/P                  | Med | CI (2.5 - 97.5)% |
|          |     |                  |                      |     |                  |
|          |     |                  |                      |     |                  |

**Death**

**Transfusion**

**General Medical Complications**

|                           |       |    |       |    |          |
|---------------------------|-------|----|-------|----|----------|
| Cardiovascular            |       |    | 1/206 | 1% | (0 - 3)% |
| Febrile                   |       |    |       |    |          |
| Infection                 |       |    |       |    |          |
| Infection/Local Extension |       |    |       |    |          |
| Neurologic                |       |    |       |    |          |
| Pulmonary                 |       |    |       |    |          |
| Systemic - Abscess        |       |    |       |    |          |
| UTI                       | 1/105 | 2% |       |    | (0 - 6)% |

**Operative Complications**

|                                      |  |  |       |     |            |
|--------------------------------------|--|--|-------|-----|------------|
| Bladder Injury                       |  |  | 2/206 | 15% | (10 - 22)% |
| Bleeding                             |  |  |       |     |            |
| Bleeding - Acute                     |  |  |       |     |            |
| Bleeding - Hematoma                  |  |  | 1/179 | 4%  | (2 - 8)%   |
| Bowel Injury                         |  |  |       |     |            |
| Erosion Extrusion                    |  |  |       |     |            |
| Erosion Extrusion - Unknown          |  |  | 1/206 | 7%  | (4 - 11)%  |
| Erosion Extrusion - Urethral-Bladder |  |  | 1/206 | 3%  | (1 - 6)%   |
| Erosion Extrusion - Vaginal          |  |  |       |     |            |
| Nerve Injury                         |  |  |       |     |            |
| Operative CX - Other                 |  |  |       |     |            |
| Osteomyelitis                        |  |  |       |     |            |
| Ureteral Injury                      |  |  |       |     |            |
| Urethral Injury                      |  |  | 2/206 | 2%  | (0 - 9)%   |
| Urinary Tract Injury NS              |  |  |       |     |            |
| Vaginal Operative CX                 |  |  | 2/206 | 13% | (6 - 22)%  |
| Wound                                |  |  |       |     |            |
| Abdominal                            |  |  | 1/179 | 7%  | (4 - 12)%  |
| Vaginal                              |  |  |       |     |            |

**Subjective Complications**

|                     |  |  |  |  |
|---------------------|--|--|--|--|
| Pain                |  |  |  |  |
| Sexual Dysfunction  |  |  |  |  |
| Voiding Dysfunction |  |  |  |  |

**Conversion**

**Other Complications**

|  |  |       |             |
|--|--|-------|-------------|
|  |  |       |             |
|  |  | 1/206 | 3% (2 - 7)% |

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Efficacy - Cure / Dry  
 NO Prolapse

|   | SUBJECTIVE Eval |        |                  | OBJECTIVE Eval |        |                  | ANY Eval       |        |                  |
|---|-----------------|--------|------------------|----------------|--------|------------------|----------------|--------|------------------|
|   | 12 - 23 months  |        |                  | 12 - 23 months |        |                  | 12 - 23 months |        |                  |
|   | G/P             | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% |
| <b>Suspensions</b>                                    |                 |        |                  |                |        |                  |                |        |                  |
| All Open Retropubic                                   | 12/867          | 80%    | (71 - 87)%       | 6/369          | 82%    | (74 - 89)%       | 15/1085        | 82%    | (74 - 87)%       |
| Burch   | 11/862          | 79%    | (69 - 87)%       | 5/354          | 81%    | (72 - 89)%       | 14/1070        | 81%    | (73 - 87)%       |
| Laparoscopic  | 4/189           | 66%    | (40 - 87)%       | 5/234          | 74%    | (64 - 83)%       | 9/368          | 69%    | (52 - 84)%       |
| <b>Slings</b>   |                 |        |                  |                |        |                  |                |        |                  |
| Autologous fascia without bone anchors                | 2/283           | 82%    | (59 - 95)%       |                |        |                  | 4/342          | 90%    | (76 - 98)%       |
| Autologous vaginal wall slings w/without bone anchors | 1/39            | 79%    | (65 - 90)%       |                |        |                  | 1/39           | 79%    | (65 - 90)%       |
| Autologous vaginal wall slings with bone anchors      |                 |        |                  |                |        |                  |                |        |                  |
| Cadaveric without bone anchors                        | 1/104           | 74%    | (65 - 82)%       |                |        |                  | 1/104          | 74%    | (65 - 82)%       |
| Synthetic at bladder neck with bone anchors           | 1/24            | 91%    | (76 - 98)%       |                |        |                  | 2/34           | 88%    | (71 - 97)%       |
| Synthetic at bladder neck without bone anchors        |                 |        |                  |                |        |                  |                |        |                  |
| Synthetic at midurethra                               | 10/917          | 85%    | (79 - 90)%       | 6/756          | 88%    | (85 - 91)%       | 14/1215        | 84%    | (78 - 89)%       |
| <b>Injectables</b>                                    |                 |        |                  |                |        |                  |                |        |                  |
| Collagen  | 4/207           | 50%    | (39 - 61)%       | 4/128          | 55%    | (44 - 64)%       | 7/340          | 48%    | (41 - 55)%       |
|   | G/P             | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% |
| <b>Artificial Sphincter</b>                           |                 |        |                  |                |        |                  |                |        |                  |

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

SUI Guideline Update Panel

Efficacy - Cure / Dry  
 NO Prolapse

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors  
 Cadaveric without bone anchors  
 Synthetic at bladder neck with bone anchors  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra

**Injectables**

Collagen

**Artificial Sphincter**

**SUBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 6/478 | 74%    | (60 - 85)%       |
| 5/450 | 74%    | (58 - 87)%       |
| 4/172 | 74%    | (61 - 85)%       |

**OBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 2/137 | 81%    | (70 - 90)%       |
| 2/137 | 81%    | (70 - 89)%       |
| 2/53  | 56%    | (31 - 80)%       |

**ANY Eval**

24 - 47 months

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 13/803 | 76%    | (68 - 82)%       |
| 12/775 | 76%    | (68 - 83)%       |
| 4/172  | 74%    | (61 - 85)%       |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 3/125 | 82%    | (74 - 89)%       |
|       |        |                  |
| 1/58  | 79%    | (68 - 88)%       |
| 1/63  | 71%    | (59 - 81)%       |
|       |        |                  |
| 3/101 | 69%    | (55 - 81)%       |
| 2/188 | 67%    | (43 - 86)%       |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
|       |        |                  |
|       |        |                  |
|       |        |                  |
|       |        |                  |
| 4/62  | 60%    | (43 - 75)%       |
| 3/258 | 84%    | (76 - 89)%       |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 6/232 | 81%    | (72 - 88)%       |
|       |        |                  |
| 1/58  | 79%    | (68 - 88)%       |
| 2/71  | 80%    | (43 - 98)%       |
|       |        |                  |
| 9/349 | 73%    | (64 - 80)%       |
| 7/483 | 81%    | (72 - 88)%       |

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 1/26 | 39%    | (22 - 58)%       |

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 3/95 | 42%    | (28 - 57)%       |

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 4/210 | 32%    | (24 - 42)%       |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P | Median | CI (2.5 - 97.5)% |
|-----|--------|------------------|
|     |        |                  |

| G/P  | Median | CI (2.5 - 97.5)% |
|------|--------|------------------|
| 3/78 | 83%    | (71 - 91)%       |

Note: **G/P**: **G** = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

SUI Guideline Update Panel

Efficacy - Cure / Dry  
 NO Prolapse

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

**SUBJECTIVE Eval**  
 48 months and greater

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 10/691 | 65%    | (55 - 74)%       |
| 7/598  | 68%    | (55 - 79)%       |
|        |        |                  |

**OBJECTIVE Eval**  
 48 months and greater

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 3/157 | 69%    | (55 - 82)%       |
| 3/157 | 69%    | (55 - 82)%       |
|       |        |                  |

**ANY Eval**  
 48 months and greater

| G/P     | Median | CI (2.5 - 97.5)% |
|---------|--------|------------------|
| 17/1259 | 73%    | (64 - 77)%       |
| 13/1065 | 73%    | (65 - 80)%       |
|         |        |                  |

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors  
 Cadaveric without bone anchors  
 Synthetic at bladder neck with bone anchors  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra

**G/P Median CI (2.5 - 97.5)%**

|       |     |            |
|-------|-----|------------|
| 2/284 | 71% | (38 - 93)% |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |

**G/P Median CI (2.5 - 97.5)%**

|      |     |            |
|------|-----|------------|
|      |     |            |
|      |     |            |
|      |     |            |
|      |     |            |
|      |     |            |
|      |     |            |
| 1/80 | 85% | (76 - 92)% |

**G/P Median CI (2.5 - 97.5)%**

|       |     |             |
|-------|-----|-------------|
| 4/368 | 82% | (67 - 93)%  |
| 1/29  | 96% | (85 - 100)% |
|       |     |             |
|       |     |             |
| 1/27  | 92% | (78 - 98)%  |
|       |     |             |
| 3/199 | 84% | (77 - 89)%  |

**Injectables**

Collagen

**G/P Median CI (2.5 - 97.5)%**

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

**G/P Median CI (2.5 - 97.5)%**

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

**G/P Median CI (2.5 - 97.5)%**

|      |     |            |
|------|-----|------------|
| 1/40 | 30% | (18 - 45)% |
|------|-----|------------|

**Artificial Sphincter**

**G/P Median CI (2.5 - 97.5)%**

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

**G/P Median CI (2.5 - 97.5)%**

|  |  |  |
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**G/P Median CI (2.5 - 97.5)%**

|  |  |  |
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|  |  |  |
|--|--|--|

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups



SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved  
 NO Prolapse

|   | SUBJECTIVE Eval |        |                  | OBJECTIVE Eval |        |                  | ANY Eval       |        |                  |
|---|-----------------|--------|------------------|----------------|--------|------------------|----------------|--------|------------------|
|   | 12 - 23 months  |        |                  | 12 - 23 months |        |                  | 12 - 23 months |        |                  |
|   | G/P             | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% |
| <b>Suspensions</b>                                    |                 |        |                  |                |        |                  |                |        |                  |
| All Open Retropubic                                   | 13/950          | 86%    | (81 - 90)%       | 6/431          | 84%    | (78 - 89)%       | 16/1168        | 86%    | (82 - 90)%       |
| Burch   | 12/935          | 86%    | (81 - 89)%       | 6/431          | 84%    | (78 - 89)%       | 15/1143        | 86%    | (81 - 89)%       |
| Laparoscopic  | 6/242           | 89%    | (83 - 94)%       | 7/287          | 77%    | (66 - 86)%       | 10/370         | 87%    | (79 - 93)%       |
| <b>Slings</b>   |                 |        |                  |                |        |                  |                |        |                  |
| Autologous fascia without bone anchors                | 2/283           | 92%    | (88 - 96)%       |                |        |                  | 4/342          | 93%    | (89 - 95)%       |
| Autologous vaginal wall slings w/without bone anchors | 1/39            | 79%    | (65 - 90)%       |                |        |                  | 1/39           | 79%    | (65 - 90)%       |
| Autologous vaginal wall slings with bone anchors      |                 |        |                  |                |        |                  |                |        |                  |
| Cadaveric without bone anchors                        | 1/104           | 93%    | (87 - 97)%       |                |        |                  | 1/104          | 93%    | (87 - 97)%       |
| Synthetic at bladder neck with bone anchors           | 1/24            | 91%    | (76 - 98)%       |                |        |                  | 2/34           | 88%    | (71 - 97)%       |
| Synthetic at bladder neck without bone anchors        |                 |        |                  |                |        |                  |                |        |                  |
| Synthetic at midurethra                               | 10/917          | 90%    | (86 - 94)%       | 6/674          | 89%    | (86 - 92)%       | 13/1166        | 88%    | (82 - 92)%       |
| <b>Injectables</b>                                    |                 |        |                  |                |        |                  |                |        |                  |
| Collagen  | 4/207           | 76%    | (69 - 82)%       | 4/128          | 57%    | (46 - 68)%       | 7/340          | 69%    | (62 - 75)%       |
|   | G/P             | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% | G/P            | Median | CI (2.5 - 97.5)% |
| <b>Artificial Sphincter</b>                           |                 |        |                  |                |        |                  |                |        |                  |

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved  
 NO Prolapse

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

**SUBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 6/478 | 82%    | (73 - 90)%       |
| 5/450 | 83%    | (73 - 91)%       |
| 4/172 | 74%    | (61 - 85)%       |

**OBJECTIVE Eval**

24 - 47 months

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 2/137 | 81%    | (70 - 89)%       |
| 2/137 | 81%    | (70 - 89)%       |
| 2/53  | 56%    | (31 - 80)%       |

**ANY Eval**

24 - 47 months

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 13/903 | 83%    | (77 - 88)%       |
| 12/775 | 84%    | (77 - 89)%       |
| 4/172  | 74%    | (61 - 85)%       |

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors  
 Cadaveric without bone anchors  
 Synthetic at bladder neck with bone anchors  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra

G/P Median CI (2.5 - 97.5)%

|       |     |            |
|-------|-----|------------|
| 3/125 | 92% | (81 - 98)% |
|       |     |            |
| 1/58  | 79% | (68 - 88)% |
| 1/63  | 78% | (66 - 87)% |
|       |     |            |
| 3/101 | 87% | (72 - 96)% |
| 2/188 | 71% | (24 - 97)% |

G/P Median CI (2.5 - 97.5)%

|       |     |            |
|-------|-----|------------|
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |
| 4/62  | 60% | (43 - 75)% |
| 3/258 | 89% | (78 - 96)% |

G/P Median CI (2.5 - 97.5)%

|       |     |            |
|-------|-----|------------|
| 6/232 | 92% | (84 - 96)% |
|       |     |            |
| 1/58  | 79% | (68 - 88)% |
| 2/72  | 80% | (60 - 93)% |
|       |     |            |
| 9/349 | 80% | (71 - 88)% |
| 9/587 | 92% | (84 - 97)% |

**Injectables**

Collagen

G/P Median CI (2.5 - 97.5)%

|      |     |            |
|------|-----|------------|
| 1/26 | 69% | (50 - 84)% |
|------|-----|------------|

G/P Median CI (2.5 - 97.5)%

|      |     |            |
|------|-----|------------|
| 3/95 | 45% | (29 - 61)% |
|------|-----|------------|

G/P Median CI (2.5 - 97.5)%

|       |     |            |
|-------|-----|------------|
| 4/210 | 55% | (41 - 69)% |
|-------|-----|------------|

G/P Median CI (2.5 - 97.5)%

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|--|--|--|
|  |  |  |
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G/P Median CI (2.5 - 97.5)%

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|  |  |  |
|--|--|--|

G/P Median CI (2.5 - 97.5)%

|      |     |            |
|------|-----|------------|
| 3/78 | 91% | (81 - 97)% |
|------|-----|------------|

**Artificial Sphincter**

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved  
 NO Prolapse

**Suspensions**

All Open Retropubic  
 Burch  
 Laparoscopic

**SUBJECTIVE Eval**

48 months and greater

| G/P    | Median | CI (2.5 - 97.5)% |
|--------|--------|------------------|
| 10/691 | 79%    | (69 - 86)%       |
| 7/598  | 84%    | (76 - 90)        |
|        |        |                  |

**OBJECTIVE Eval**

48 months and greater

| G/P   | Median | CI (2.5 - 97.5)% |
|-------|--------|------------------|
| 3/157 | 69%    | (55 - 82)%       |
| 3/157 | 69%    | (55 - 82)%       |
|       |        |                  |

**ANY Eval**

48 months and greater

| G/P     | Median | CI (2.5 - 97.5)% |
|---------|--------|------------------|
| 17/1259 | 79%    | (73 - 85)%       |
| 13/1065 | 83%    | (76 - 88)%       |
|         |        |                  |

**Slings**

Autologous fascia without bone anchors  
 Autologous vaginal wall slings w/without bone anchors  
 Autologous vaginal wall slings with bone anchors  
 Cadaveric without bone anchors  
 Synthetic at bladder neck with bone anchors  
 Synthetic at bladder neck without bone anchors  
 Synthetic at midurethra

G/P Median CI (2.5 - 97.5)%

|       |     |            |
|-------|-----|------------|
| 2/284 | 81% | (63 - 93)% |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |
|       |     |            |

G/P Median CI (2.5 - 97.5)%

|      |     |           |
|------|-----|-----------|
|      |     |           |
|      |     |           |
|      |     |           |
|      |     |           |
|      |     |           |
|      |     |           |
| 1/80 | 89% | (80 - 94) |

G/P Median CI (2.5 - 97.5)%

|       |     |             |
|-------|-----|-------------|
| 4/368 | 86% | (78 - 92)%  |
| 1/29  | 96% | (85 - 100)% |
|       |     |             |
|       |     |             |
| 1/27  | 92% | (78 - 98)%  |
|       |     |             |
| 3/199 | 91% | (84 - 96)%  |

**Injectables**

Collagen

G/P Median CI (2.5 - 97.5)%

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

G/P Median CI (2.5 - 97.5)%

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

G/P Median CI (2.5 - 97.5)%

|      |     |            |
|------|-----|------------|
| 1/40 | 70% | (55 - 82)% |
|------|-----|------------|

**Artificial Sphincter**

G/P Median CI (2.5 - 97.5)%

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|--|--|--|
|  |  |  |
|--|--|--|

G/P Median CI (2.5 - 97.5)%

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

G/P Median CI (2.5 - 97.5)%

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|  |  |  |
|--|--|--|

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

SUI Guideline Update Panel

Retention  
 NO Prolapse

| Suspensions |                     | > 28 days or Intervention |        |                  |
|-------------|---------------------|---------------------------|--------|------------------|
|             |                     | G/P                       | Median | CI (2.5 - 97.5)% |
|             | All Open Retropubic | 8/619                     | 4%     | (1 - 8)%         |
|             | Burch               | 5/347                     | 3%     | (1 - 7)%         |
|             | Laparoscopic        | 5/188                     | 4%     | (1 - 8)%         |

| Slings |   | G/P     | Median | CI (2.5 - 97.5)% |
|--------|---|---------|--------|------------------|
|        | Autologous fascia without bone anchors                | 8/480   | 8%     | (4 - 15)%        |
|        | Autologous vaginal wall slings w/without bone anchors | 2/68    | 2%     | (0 - 8)%         |
|        | Synthetic at bladder neck without bone anchors        | 4/360   | 9%     | (5 - 15)%        |
|        | Synthetic at midurethra                               | 17/2119 | 3%     | (2 - 4)%         |

| Injectables |          | G/P   | Median | CI (2.5 - 97.5)% |
|-------------|----------|-------|--------|------------------|
|             | Collagen | 2/104 | 1%     | (0 - 5)%         |

Note: **G/P:** **G** = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

## Urge Incontinence

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**SUI Guideline Update Panel**

**Urgency  
NO Prolapse**

**Urgency Symptons**

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

| New Onset |        |                  | Pre-Existing |        |                  | Unspecified |        |                  |
|-----------|--------|------------------|--------------|--------|------------------|-------------|--------|------------------|
| G/P       | Median | CI (2.5 - 97.5)% | G/P          | Median | CI (2.5 - 97.5)% | G/P         | Median | CI (2.5 - 97.5)% |
| 5/476     | 15%    | (7 - 27)%        | 1/90         | 0%     | (0 - 3)%         | 1/102       | 0%     | (0 - 2)%         |
| 5/476     | 15%    | (7 - 27)%        | 1/90         | 0%     | (0 - 3)%         | 1/102       | 0%     | (0 - 2)%         |
|           |        |                  |              |        |                  |             |        |                  |

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Cadaveric without bone anchors  
Synthetic at bladder neck with bone anchors  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra

|       |     |            |       |     |            |       |     |            |
|-------|-----|------------|-------|-----|------------|-------|-----|------------|
| 5/228 | 16% | (10 - 23)% | 3/63  | 41% | (28 - 55)% |       |     |            |
|       |     |            |       |     |            |       |     |            |
| 1/8   | 14% | (1 - 45)%  |       |     |            |       |     |            |
|       |     |            |       |     |            |       |     |            |
| 3/108 | 13% | (6 - 23)%  |       |     |            |       |     |            |
| 4/190 | 14% | (5 - 30)%  | 4/178 | 38% | (27 - 50)% | 2/532 | 45% | (11 - 83)% |

**Injectables**

Collagen

|  |  |  |  |  |  |  |  |  |
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**SUI Guideline Update Panel**

**Urgency  
NO Prolapse**

**Suspensions**

All Open Retropubic  
Burch  
Laparoscopic

**Slings**

Autologous fascia without bone anchors  
Autologous vaginal wall slings w/without bone anchors  
Cadaveric without bone anchors  
Synthetic at bladder neck with bone anchors  
Synthetic at bladder neck without bone anchors  
Synthetic at midurethra

**Injectables**

Collagen

**Unspecified Urgency**

| New Onset |        |                  | Pre-Existing |        |                  | Unspecified |        |                  |
|-----------|--------|------------------|--------------|--------|------------------|-------------|--------|------------------|
| G/P       | Median | CI (2.5 - 97.5)% | G/P          | Median | CI (2.5 - 97.5)% | G/P         | Median | CI (2.5 - 97.5)% |
| 2/95      | 28%    | (18 - 40)%       | 2/116        | 23%    | (11 - 39)%       | 1/36        | 9%     | (2 - 21)%        |
| 2/95      | 28%    | (18 - 40)%       | 2/116        | 23%    | (11 - 39)%       | 1/36        | 9%     | (2 - 21)%        |
|           |        |                  |              |        |                  | 2/55        | 9%     | (2 - 23)%        |

|      |     |            |      |     |            |  |  |  |
|------|-----|------------|------|-----|------------|--|--|--|
| 1/10 | 11% | (1 - 38)%  | 1/15 | 40% | (19 - 65)% |  |  |  |
|      |     |            |      |     |            |  |  |  |
|      |     |            |      |     |            |  |  |  |
|      |     |            |      |     |            |  |  |  |
| 1/53 | 32% | (21 - 45)% |      |     |            |  |  |  |
|      |     |            |      |     |            |  |  |  |

|      |     |           |  |  |  |      |     |            |
|------|-----|-----------|--|--|--|------|-----|------------|
| 3/86 | 17% | (6 - 35)% |  |  |  | 1/28 | 36% | (20 - 54)% |
|------|-----|-----------|--|--|--|------|-----|------------|

SUI Guideline Update Panel  
Complications  
NO Prolapse

Death

Transfusion

General Medical Complications

Cardiovascular

Dermatologic

Febrile

Infection

Infection/Local Extension

Neurologic

Pulmonary

Systemic - Abscess

UTI

Operative Complications

Bladder Injury

Bleeding

Bleeding - Acute

Bleeding - Hematoma

Bowel Injury

Erosion Extrusion - Unknown

Erosion Extrusion - Urethral-Bladder

Erosion Extrusion - Vaginal

Nerve Injury

Osteomyelitis

Ureteral Injury

Urethral Injury

Urinary Tract Injury NS

Vaginal Operative CX

Wound

Wound - Abdominal

Wound - Vaginal

Subjective Complications

Pain

Sexual Dysfunction

Voiding Dysfunction

Conversion

Other Complications

Suspensions

All Retropubic Suspensions

Burch Suspension

Laparoscopic Suspension

G/P Med CI (2.5 - 97.5)%

G/P Med CI (2.5 - 97.5)%

G/P Med CI (2.5 - 97.5)%

2/170 3% (0 - 14)%

2/170 3% (0 - 14)%

6/321 6% (2 - 12)%

4/169 9%§ (3 - 19)%

1/24 5% (0 - 18)%

6/592 2% (1 - 4)%

3/294 3% (1 - 8)%

7/426 8% (5 - 12)%

3/113 11% (5 - 20)%

1/60 0% (0 - 4)%

1/98 2% (0 - 6)%

1/98 2% (0 - 6)%

1/31 4% (0 - 14)%

\*

\*

1/113 1% (0 - 4)%

1/113 1% (0 - 4)%

1/15 8% (1 - 27)%

1/51 2% (0 - 9)%

1/62 7% (2 - 15)%

1/62 7% (2 - 15)%

17/1442 13% (9 - 19)%

10/978 15% (8 - 24)%

1/51 2% (0 - 9)%

10/887 4% (2 - 7)%

7/589 6% (2 - 12)%

5/165 5% (2 - 10)%

3/433 4% (1 - 9)%

2/334 2% (0 - 6)%

6/484 3% (2 - 6)%

5/469 3% (1 - 5)%

1/51 2% (0 - 9)%

1/31 4% (0 - 14)%

1/31 4% (0 - 14)%

1/31 4% (0 - 14)%

2/102 19%§ (1 - 70)%

\*

\*

5/1739 1% (1 - 2)%

4/1640 1% (1 - 2)%

3/57 11% (1 - 42)%

2/55 2% (0 - 10)%

1/60 2% (0 - 8)%

13/1229 6% (4 - 7)%

8/793 6% (4 - 9)%

1/51 2% (0 - 9)%

9/761 4% (3 - 6)%

5/449 4% (2 - 7)%

9/980 5% (3 - 8)%

6/756 6% (3 - 12)%

\*

8/989 4% (2 - 6)%

5/801 3% (2 - 4)%

6/636 9% (5 - 15)%

5/583 10% (5 - 18)%

1/60 5% (1 - 13)%

1/17 7% (1 - 24)%

1/17 7% (1 - 24)%

3/184 5% (2 - 9)%

3/253 5% (0 - 20)%

2/154 14% (0 - 66)%

1/51 2% (0 - 9)%

Note: **G/P:** **G** = Number of Groups/Treatment arms extracted **P** = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

SUI Guideline Update Panel  
Complications  
NO Prolapse

Death

Transfusion

General Medical Complications

Cardiovascular

Dermatologic

Febrile

Infection

Infection/Local Extension

Neurologic

Pulmonary

Systemic - Abscess

UTI

Operative Complications

Bladder Injury

Bleeding

Bleeding - Acute

Bleeding - Hematoma

Bowel Injury

Erosion Extrusion - Unknown

Erosion Extrusion - Urethral-Bladder

Erosion Extrusion - Vaginal

Nerve Injury

Osteomyelitis

Ureteral Injury

Urethral Injury

Urinary Tract Injury NS

Vaginal Operative CX

Wound

Wound - Abdominal

Wound - Vaginal

Subjective Complications

Pain

Sexual Dysfunction

Voiding Dysfunction

Conversion

Other Complications

| Slings               |     |                  |                                |     |                  |                      |     |                  |
|----------------------|-----|------------------|--------------------------------|-----|------------------|----------------------|-----|------------------|
| Autologous fascia    |     |                  | Autologous Vaginal Wall Slings |     |                  | Cadaveric            |     |                  |
| without Bone Anchors |     |                  | with/without Bone anchors      |     |                  | without Bone Anchors |     |                  |
| G/P                  | Med | CI (2.5 - 97.5)% | G/P                            | Med | CI (2.5 - 97.5)% | G/P                  | Med | CI (2.5 - 97.5)% |
| 1/90                 | 0%  | (0 - 3)%         |                                |     |                  |                      |     |                  |
| 3/194                | 4%  | (1 - 11)%        |                                |     |                  | 1/63                 | 0%  | (0 - 4)%         |
| 2/338                | 2%  | (0 - 5)%         |                                |     |                  |                      |     |                  |
|                      |     |                  |                                |     |                  |                      |     |                  |
| 1/71                 | 0%  | (0 - 3)%         |                                |     |                  | 1/63                 | 7%  | (2 - 14)%        |
|                      |     |                  |                                |     |                  |                      |     |                  |
| 1/30                 | 4%§ | (0 - 15)%        |                                |     |                  |                      |     |                  |
| 1/91                 | 1%  | (0 - 5)%         |                                |     |                  |                      |     |                  |
|                      |     |                  |                                |     |                  | 1/104                | 2%  | (0 - 6)%         |
| 5/241                | 16% | (6 - 31)%        | 2/402                          | 4%  | (2 - 7)%         | 1/63                 | 7%  | (2 - 14)%        |

|       |    |           |       |    |          |       |          |
|-------|----|-----------|-------|----|----------|-------|----------|
| 6/423 | 4% | (2 - 9)%  | 1/29  | 1% | (0 - 8)% |       |          |
|       |    |           |       |    |          |       |          |
| 1/20  | 6% | (1 - 21)% |       |    |          |       |          |
| 1/247 | 1% | (0 - 3)%  |       |    |          | 1/104 | 1%       |
|       |    |           |       |    |          |       | (0 - 4)% |
| 1/33  | 1% | (0 - 7)%  |       |    |          |       | *        |
| 4/370 | 2% | (0 - 7)%  |       |    |          | 1/63  | 0%       |
|       |    |           |       |    |          |       | (0 - 4)% |
|       |    |           | 1/373 | 2% | (1 - 4)% |       | *        |
|       |    |           |       |    |          | 1/104 | 1%       |
|       |    |           |       |    |          |       | (0 - 4)% |
|       |    |           |       |    |          |       |          |
|       |    |           |       |    |          |       |          |
|       |    |           |       |    |          |       |          |
|       |    |           |       |    |          |       |          |
|       |    |           |       |    |          |       |          |
| 2/111 | 8% | (3 - 16)% |       |    |          |       |          |
| 1/247 | 1% | (0 - 3)%  | 2/402 | 5% | (3 - 8)% |       |          |
|       |    |           |       |    |          |       |          |

|       |     |           |  |  |     |                 |
|-------|-----|-----------|--|--|-----|-----------------|
| 3/63  | 10% | (1 - 35)% |  |  |     |                 |
| 4/105 | 8%  | (3 - 16)% |  |  |     |                 |
|       | *   |           |  |  | 1/8 | 38%§ (12 - 71)% |

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Note: **G/P**: **G** = Number of Groups/Treatment arms extracted **P** = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

## Appendix A16-Complications rates - No Prolapse

## SUI Guideline Update Panel

### Complications

#### NO Prolapse

## Slings

### Synthetic at Bladder Neck

[illegible]

## Operative Complications

|                                      |      |       |           |       |    |          |   |
|--------------------------------------|------|-------|-----------|-------|----|----------|---|
| Bladder Injury                       | 1/11 | 10%\$ | (1 - 35)% |       |    |          |   |
| Bleeding                             |      |       |           |       |    |          |   |
| Bleeding - Acute                     |      |       |           |       |    |          |   |
| Bleeding - Hematoma                  |      |       |           |       |    |          |   |
| Bowel Injury                         |      |       |           |       |    |          |   |
| Erosion Extrusion - Unknown          |      |       |           |       |    |          |   |
| Erosion Extrusion - Urethral-Bladder |      |       |           |       |    |          | * |
| Erosion Extrusion - Vaginal          | 1/10 | 21%\$ | (4 - 50)% |       |    |          | * |
| Nerve Injury                         |      |       |           |       |    |          |   |
| Osteomyelitis                        |      | *     |           | 1/108 | 3% | (1 - 7)% |   |
| Ureteral Injury                      |      |       |           |       |    |          |   |
| Urethral Injury                      |      |       |           |       |    |          |   |
| Urinary Tract Injury NS              |      |       |           |       |    |          |   |
| Vaginal Operative CX                 |      |       |           |       |    |          |   |
| Wound                                |      |       |           |       |    |          |   |
| Wound - Abdominal                    |      |       |           |       |    |          |   |
| Wound - Vaginal                      |      |       |           |       |    |          |   |

## Subjective Complications

|                     |  |  |  |  |  |
|---------------------|--|--|--|--|--|
| Pain                |  |  |  |  |  |
| Sexual Dysfunction  |  |  |  |  |  |
| Voiding Dysfunction |  |  |  |  |  |

## Conversion

|                     |  |  |  |  |  |
|---------------------|--|--|--|--|--|
|                     |  |  |  |  |  |
| Other Complications |  |  |  |  |  |

## Other Complications

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.



SUI Guideline Update Panel  
Complications  
NO Prolapse

Death

Transfusion

General Medical Complications

- Cardiovascular
- Dermatologic
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Wound - Abdominal
- Wound - Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Slings

Synthetic at Bladder Neck

| without Bone Anchors |     |                  | Synthetic at Midurethra |     |                  | Other Sling |     |                  |
|----------------------|-----|------------------|-------------------------|-----|------------------|-------------|-----|------------------|
| G/P                  | Med | CI (2.5 - 97.5)% | G/P                     | Med | CI (2.5 - 97.5)% | G/P         | Med | CI (2.5 - 97.5)% |
|                      |     |                  | 1/25                    | 1%  | (0 - 9)%         |             |     |                  |
| 1/200                | 1%  | (0 - 3)%         | 3/569                   | 2%  | (1 - 4)%         |             |     |                  |

|       |     |           |       |    |           |  |   |  |
|-------|-----|-----------|-------|----|-----------|--|---|--|
|       |     |           | 2/261 | 1% | (0 - 3)%  |  |   |  |
|       |     |           |       |    |           |  |   |  |
|       |     |           |       |    |           |  | * |  |
|       |     |           |       |    |           |  |   |  |
|       |     |           | 2/174 | 7% | (4 - 13)% |  |   |  |
|       |     |           |       |    |           |  |   |  |
|       |     |           |       |    |           |  |   |  |
| 2/315 | 3%  | (1 - 5)%  | 1/25  | 1% | (0 - 9)%  |  |   |  |
| 2/224 | 10% | (2 - 27)% | 9/771 | 8% | (5 - 13)% |  |   |  |

|       |      |           |         |    |           |  |   |  |
|-------|------|-----------|---------|----|-----------|--|---|--|
| 1/200 | 1%   | (0 - 2)%  | 23/1925 | 6% | (4 - 8)%  |  |   |  |
|       |      |           |         |    |           |  |   |  |
|       |      |           | 6/705   | 3% | (1 - 5)%  |  |   |  |
|       |      |           | 7/1035  | 3% | (2 - 4)%  |  |   |  |
|       |      |           | 3/256   | 1% | (0 - 4)%  |  |   |  |
| 2/501 | 17%§ | (9 - 28)% | 6/621   | 1% | (0 - 3)%  |  |   |  |
| 3/346 | 3%   | (1 - 9)%  |         |    |           |  |   |  |
| 6/591 | 8%   | (4 - 15)% | 9/891   | 7% | (2 - 15)% |  | * |  |
| 1/200 | 1%   | (0 - 2)%  | 1/404   | 0% | (0 - 1)%  |  |   |  |
|       |      |           |         |    |           |  |   |  |
|       |      |           |         |    |           |  |   |  |
|       |      |           |         | *  |           |  | * |  |
|       |      |           |         |    |           |  |   |  |
|       |      |           | 2/302   | 2% | (0 - 7)%  |  |   |  |
| 2/385 | 7%   | (3 - 14)% | 3/280   | 2% | (1 - 5)%  |  |   |  |
|       |      |           | 2/75    | 2% | (0 - 8)%  |  |   |  |
|       |      |           | 4/189   | 4% | (1 - 7)%  |  |   |  |

|       |    |           |        |    |          |  |  |  |
|-------|----|-----------|--------|----|----------|--|--|--|
| 2/264 | 9% | (2 - 23)% | 2/512  | 1% | (0 - 3)% |  |  |  |
|       |    |           | 1/62   | 0% | (0 - 4)% |  |  |  |
|       |    |           | 1/1175 | 2% | (1 - 3)% |  |  |  |

|  |  |  |  |  |  |  |   |  |
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|  |  |  |  |  |  |  | * |  |
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

## SUI Guideline Update Panel

### Complications

#### NO Prolapse

|                                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|--------------------------------------|--|--|--|-------|--|--|--|------|--|--|--|-----------|--|--|--|-----------------|--|--|--|-----------|--|--|--|------|--|--|--|-----------|--|--|--|
| Death                                |  |  |  |       |  |  |  |      |  |  |  | 1/25      |  |  |  | 5%              |  |  |  | (0 - 17)% |  |  |  |      |  |  |  |           |  |  |  |
| Transfusion                          |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| General Medical Complications        |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Cardiovascular                       |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Dermatologic                         |  |  |  | 3/399 |  |  |  | 5%   |  |  |  | (1 - 17)% |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Febrile                              |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Infection                            |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Infection/Local Extension            |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Neurologic                           |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Pulmonary                            |  |  |  | 1/60  |  |  |  | 2%   |  |  |  | (0 - 8)%  |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Systemic - Abscess                   |  |  |  | 1/115 |  |  |  | 1%   |  |  |  | (0 - 4)%  |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| UTI                                  |  |  |  | 6/381 |  |  |  | 10%  |  |  |  | (5 - 17)% |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|                                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Operative Complications              |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Bladder Injury                       |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Bleeding                             |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Bleeding - Acute                     |  |  |  | 4/251 |  |  |  | 5%   |  |  |  | (3 - 8)%  |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Bleeding - Hematoma                  |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Bowel Injury                         |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Erosion Extrusion - Unknown          |  |  |  |       |  |  |  |      |  |  |  | 1/18      |  |  |  | 28%§ (11 - 51)% |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Erosion Extrusion - Urethral-Bladder |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Erosion Extrusion - Vaginal          |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Nerve Injury                         |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Osteomyelitis                        |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Ureteral Injury                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Urethral Injury                      |  |  |  | *     |  |  |  |      |  |  |  | *         |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Urinary Tract Injury NS              |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Vaginal Operative CX                 |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Wound                                |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Wound - Abdominal                    |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Wound - Vaginal                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|                                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Subjective Complications             |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Pain                                 |  |  |  | *     |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Sexual Dysfunction                   |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Voiding Dysfunction                  |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|                                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Conversion                           |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|                                      |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
| Other Complications                  |  |  |  |       |  |  |  |      |  |  |  |           |  |  |  |                 |  |  |  |           |  |  |  |      |  |  |  |           |  |  |  |
|                                      |  |  |  | 3/342 |  |  |  | 27%§ |  |  |  | (2 - 76)% |  |  |  |                 |  |  |  | 1/18      |  |  |  | 23%§ |  |  |  | (8 - 45)% |  |  |  |

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

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**Complications for Groups with Uniform SUI  
Treatment - with or without Prolapse RX**

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**Artificial Sphincter**

Acute Bleeding  
Bladder Injury  
Bowel Injury  
Death  
Fistula  
Infection - Wound  
Other Complications  
PE/DVT  
Removal of Foreign Body - other  
Urethral Erosion  
Vascular Injury  
Wound - Abdominal Minor  
Wound - Vaginal

**Autologous fascia with bone anchors - Suprapubic**

Infection - UTI  
Infection - Wound  
None (per Author)

**Autologous fascia without bone anchors**

Acute Bleeding  
Bladder Injury  
Bowel Injury  
Death  
DVT  
Dysuria  
Hematoma  
Infection  
Infection - UTI  
Infection - Wound  
None (per Author)  
Other Complications  
Pain  
PE/DVT  
Pulmonary  
Removal of Foreign Body - other  
Sexual Dysfunction  
Stitches  
Transfusion

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**Complications for Groups with Uniform SUI  
 Treatment - with or without Prolapse RX**

Urethral Erosion  
 Wound - Abdominal  
 Wound - Abdominal Major  
 Wound - Abdominal Minor  
 Wound - Vaginal Minor

**Autologous vaginal wall slings w/without bone anchors**

Acute Bleeding  
 Bladder Injury  
 Death  
 Dysuria  
 Fistula  
 Infection - Local Extension  
 Infection - UTI  
 Infection - Wound  
 MI  
 None (per Author)  
 Other Complications  
 Pain  
 Sexual Dysfunction  
 Stitches  
 Transfusion  
 Urethral Erosion  
 Wound - Abdominal  
 Wound - Abdominal Major  
 Wound - Abdominal Minor  
 Wound - Vaginal Major  
 Wound - Vaginal Minor

**Autologous vaginal wall slings with bone anchors - Suprapubic**

None (per Author)  
 Other Complications  
 Removal of Foreign Body - other  
 Wound - Abdominal Major

**Burch Suspension**

Acute Bleeding  
 Bladder Injury  
 Bowel Injury  
 Death

**American Urological Association, Inc.  
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**Complications for Groups with Uniform SUI  
 Treatment - with or without Prolapse RX**

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DVT  
 Dysuria  
 Fistula  
 Hematoma  
 Infection  
 Infection - Local Extension  
 Infection - Systemic  
 Infection - UTI  
 Infection - Wound  
 None (per Author)  
 Other Complications  
 Pain  
 PE/DVT  
 Pulmonary  
 Rectal Injury  
 Sexual Dysfunction  
 Transfusion  
 Urethral Erosion  
 Vascular Injury  
 Wound  
 Wound - Abdominal  
 Wound - Abdominal Major  
 Wound - Abdominal Minor

**Cadaveric with bone anchors**

Wound - Vaginal Major

**Cadaveric with bone anchors - Transvaginal**

Bladder Injury  
 Infection - Systemic  
 Infection - UTI  
 Other Complications  
 Pain  
 Sexual Dysfunction  
 Wound - Vaginal Minor

**Cadaveric without bone anchors**

Bladder Injury  
 Hematoma  
 Infection - UTI



## American Urological Association, Inc. SUI Guidelines Panel

## Complications for Groups with Uniform SUI Treatment - with or without Prolapse RX

Infection - Wound  
Other Complications  
Removal of Foreign Body - other  
Transfusion  
Urethral Erosion  
Wound - Abdominal  
Wound - Abdominal Major

### Collagen

Acute Bleeding  
Infection - UTI  
Infection - Wound  
None (per Author)  
Other Complications  
Pulmonary

### Cooper's ligament sling (all sling materials)

CVA  
Death  
Hematoma  
Other Complications

### Homologous tissue (dermis) with bone anchors - Transvaginal

Acute Bleeding  
Bladder Injury  
Bowel Injury  
Infection - Local Extension  
Other Complications  
Sexual Dysfunction  
Wound - Vaginal Minor

### Homologous tissue (dermis) without bone anchors

None (per Author)  
Other Complications  
Wound - Vaginal Major

### Laparoscopic Suspension

Acute Bleeding  
Bladder Injury

**American Urological Association, Inc.  
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI  
Treatment - with or without Prolapse RX**

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Bowel Injury  
Dysuria  
Fistula  
Hematoma  
Infection  
Infection - Local Extension  
Infection - Systemic  
Infection - UTI  
Infection - Wound  
None (per Author)  
Other Complications  
Pain  
PE/DVT  
Pulmonary  
Removal of Foreign Body - other  
Sexual Dysfunction  
Stitches  
Transfusion  
Ureteral Injury  
Vascular Injury  
Wound  
Wound - Abdominal  
Wound - Abdominal Major  
Wound - Abdominal Minor  
Wound - Vaginal  
Wound - Vaginal Major

**MMK**

Hematoma  
Infection - UTI  
Infection - Wound  
Other Complications  
Pulmonary  
Sexual Dysfunction  
Stitches  
Transfusion  
Wound - Abdominal

**Open Retropubic Suspensions**

Acute Bleeding

**American Urological Association, Inc.  
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**Complications for Groups with Uniform SUI  
Treatment - with or without Prolapse RX**

Bladder Injury  
Bowel Injury  
Hematoma  
Infection - Local Extension  
Infection - Systemic  
Infection - UTI  
Infection - Wound  
Other Complications  
PE/DVT  
Transfusion  
Vascular Injury  
Wound - Abdominal Major  
Wound - Abdominal Minor

**Other degradable materials**

Death  
Hematoma  
Infection - UTI  
Other Complications  
PE/DVT

**Other Injectables**

Death  
Infection - UTI  
Other Complications  
Removal of Foreign Body - other  
Wound - Abdominal Major  
Wound - Abdominal Minor

**Other non-degradable synthetics**

Dysuria  
Infection - UTI  
Other Complications

**Other Sling**

Acute Bleeding  
Bladder Injury  
Infection  
Infection - UTI

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 SUI Guidelines Panel**

**Complications for Groups with Uniform SUI  
 Treatment - with or without Prolapse RX**

None (per Author)  
 Other Complications  
 Transfusion  
 Wound - Vaginal Major

**Other Suspensions**

Acute Bleeding  
 Bladder Injury  
 Bowel Injury  
 Dysuria  
 Hematoma  
 Infection - Systemic  
 Infection - UTI  
 Infection - Wound  
 None (per Author)  
 Other Complications  
 PE/DVT  
 Pulmonary  
 Removal of Foreign Body - other  
 Sexual Dysfunction  
 Stitches  
 Transfusion  
 Wound - Abdominal Minor

**Synthetic at bladder neck with bone anchors**

Bladder Injury  
 None (per Author)  
 Other Complications  
 Wound - Vaginal

**Synthetic at bladder neck with bone anchors - Suprapubic**

Bladder Injury  
 Infection  
 Other Complications  
 Removal of Foreign Body - other  
 Sexual Dysfunction  
 Urethral Erosion  
 Wound - Abdominal Minor

**American Urological Association, Inc.  
 SUI Guidelines Panel**

**Complications for Groups with Uniform SUI  
 Treatment - with or without Prolapse RX**

**Synthetic at bladder neck with bone anchors - Transvaginal**

Acute Bleeding  
 Bladder Injury  
 Hematoma  
 Infection - UTI  
 Infection - Wound  
 Other Complications  
 Removal of Foreign Body - other  
 Sexual Dysfunction  
 Urethral Erosion  
 Wound - Vaginal Major  
 Wound - Vaginal Minor

**Synthetic at bladder neck without bone anchors**

Acute Bleeding  
 Bladder Injury  
 Bowel Injury  
 Hematoma  
 Infection - Systemic  
 Infection - UTI  
 Infection - Wound  
 MI  
 None (per Author)  
 Other Complications  
 Pulmonary  
 Removal of Foreign Body - other  
 Sexual Dysfunction  
 Stitches  
 Transfusion  
 Urethral Erosion  
 Wound  
 Wound - Abdominal  
 Wound - Abdominal Major  
 Wound - Abdominal Minor  
 Wound - Vaginal  
 Wound - Vaginal Major  
 Wound - Vaginal Minor

**Synthetic at midurethra**

Acute Bleeding



## American Urological Association, Inc. SUI Guidelines Panel

## Complications for Groups with Uniform SUI Treatment - with or without Prolapse RX

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Bladder Injury  
 Bowel Injury  
 Death  
 Dysuria  
 Fistula  
 Hematoma  
 Infection  
 Infection - Local Extension  
 Infection - Systemic  
 Infection - UTI  
 Infection - Wound  
 MI  
 None (per Author)  
 Other Complications  
 PE/DVT  
 Removal of Foreign Body - other  
 Sexual Dysfunction  
 Transfusion  
 Urethral Erosion  
 Vascular Injury  
 Wound  
 Wound - Abdominal  
 Wound - Abdominal Major  
 Wound - Abdominal Minor  
 Wound - Vaginal  
 Wound - Vaginal Major  
 Wound - Vaginal Minor

### Transvaginal Cooper's Ligament Suspension

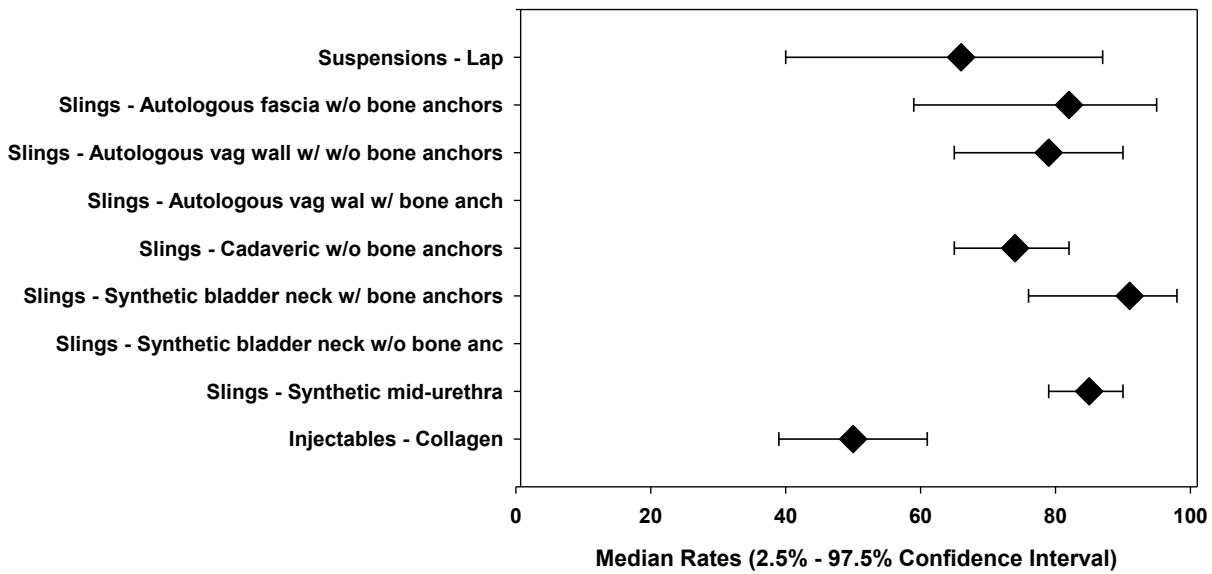
Death  
 Hematoma  
 None (per Author)  
 Other Complications  
 Wound - Vaginal Minor

### Xenograft without bone anchors

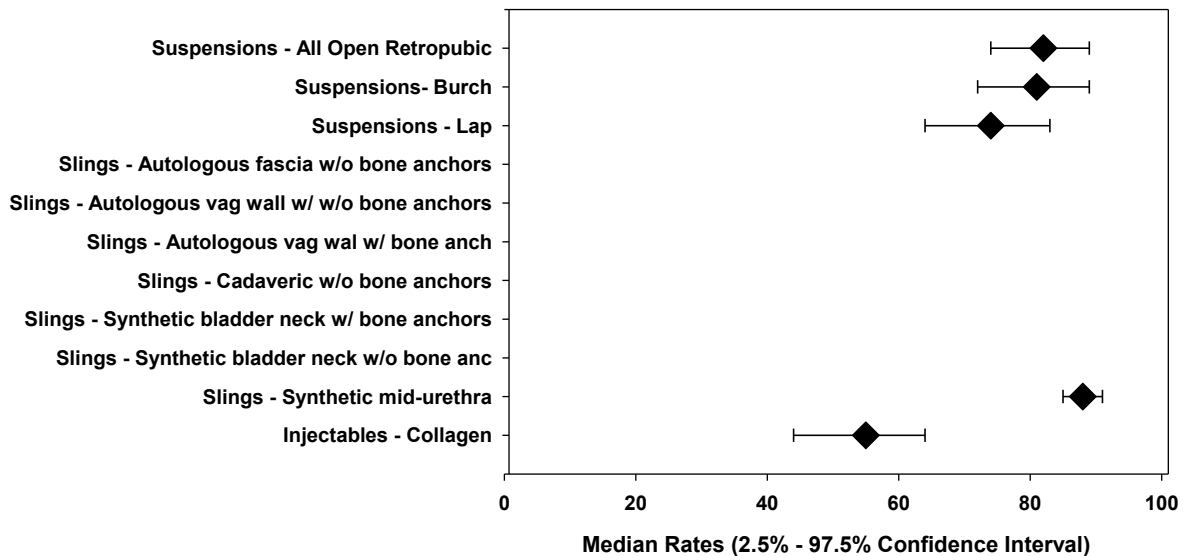
Wound - Abdominal Major  
 Wound - Vaginal Major  
 Wound - Vaginal Minor

## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 12-23 Mos

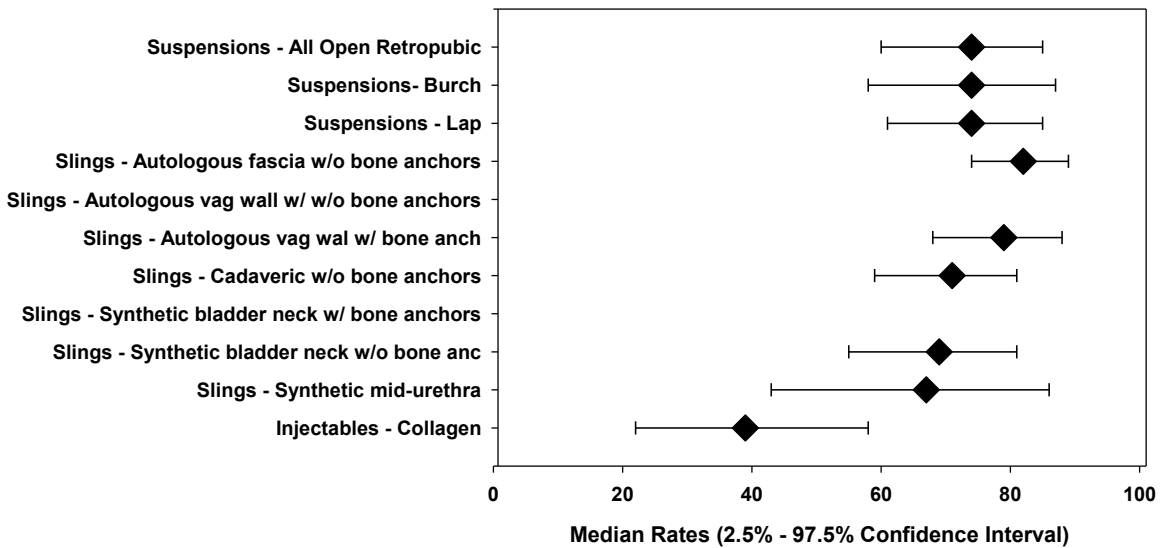


### No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 12-23 Mos

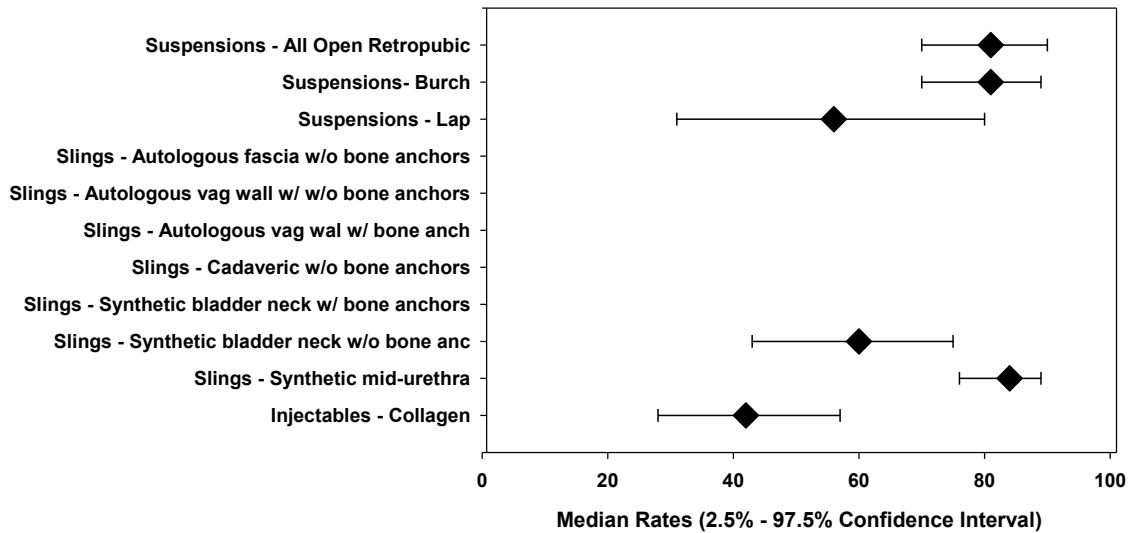


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 24-47 Mos

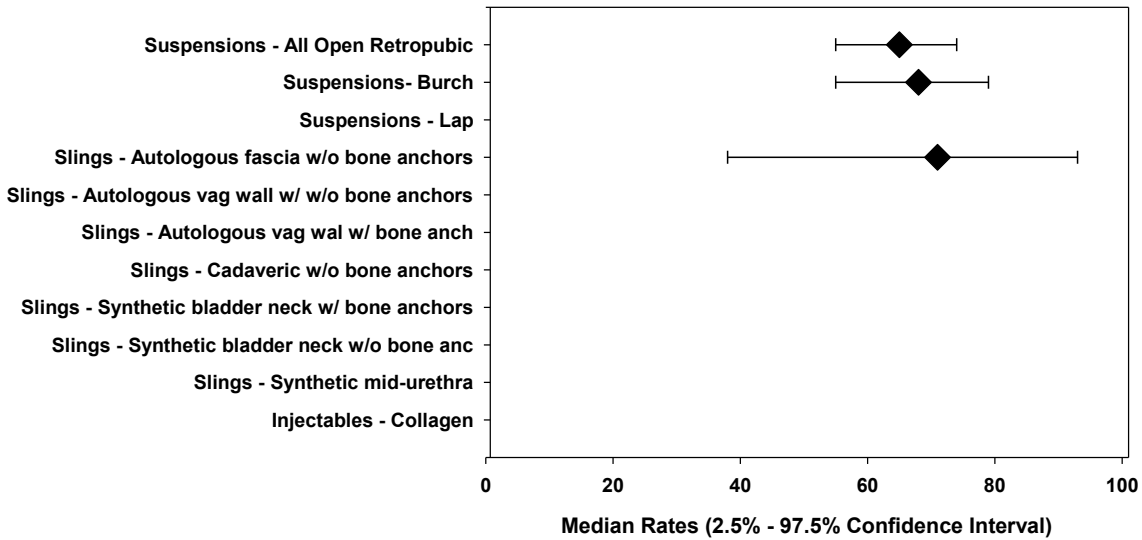


### No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 24-47 Mos

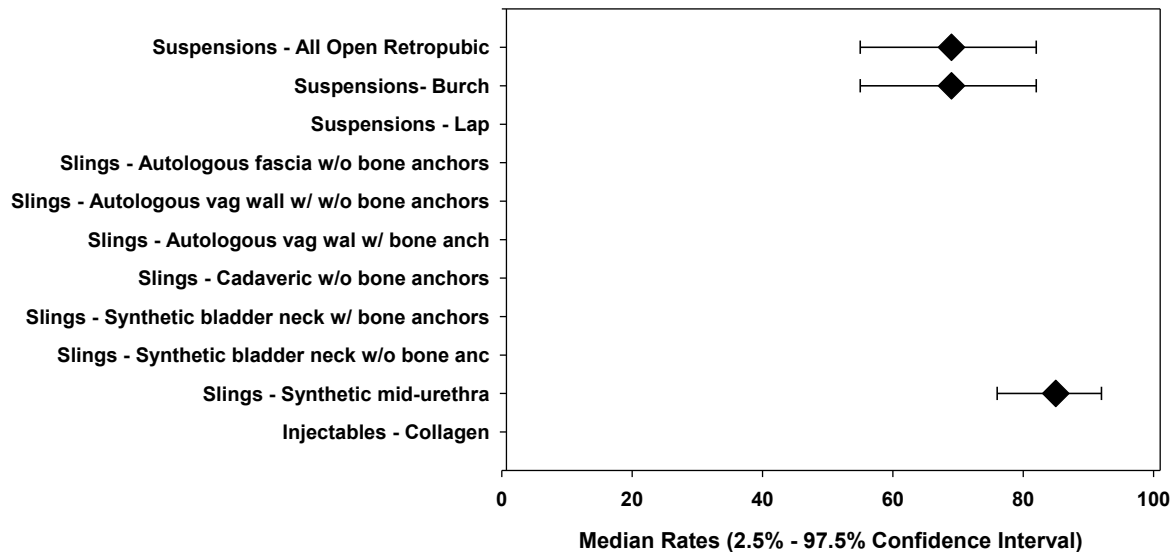


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 48+ Mos

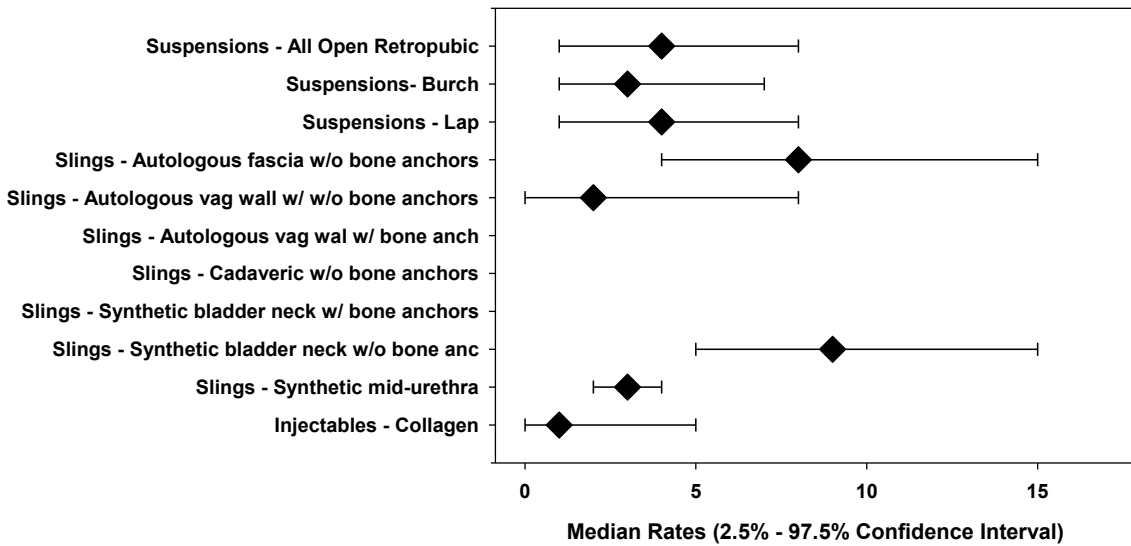


### No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 48+ Mos

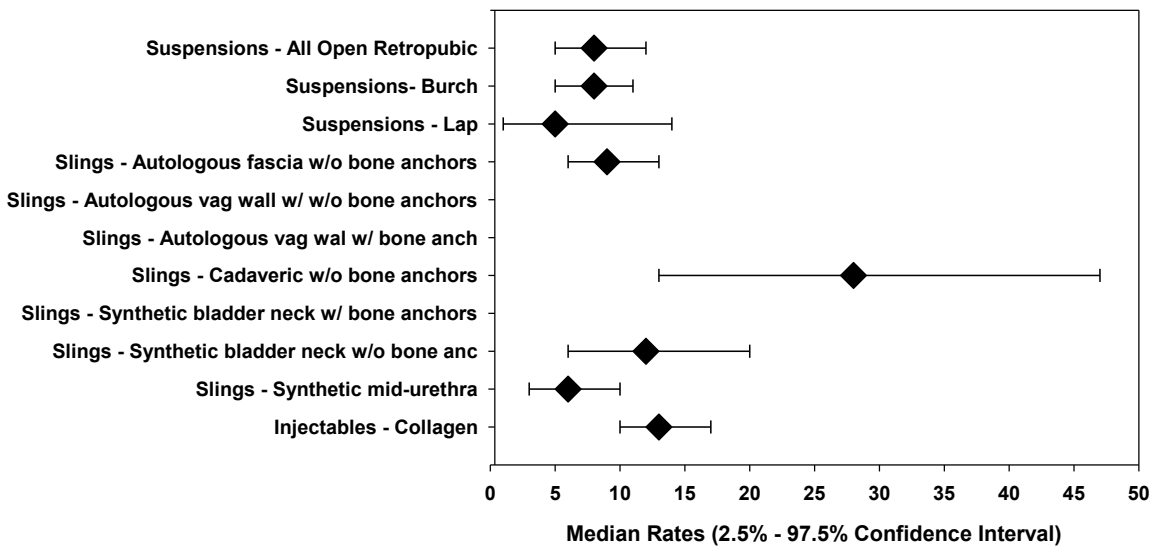


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Retention > 28 days or Intervention



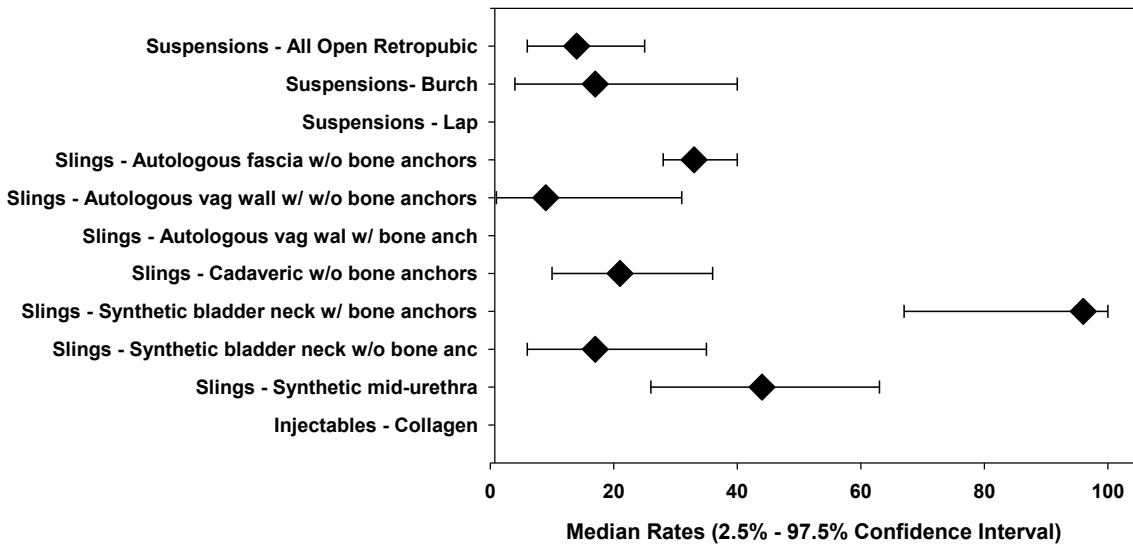
### No Prolapse Patients: Urgency Urge Incontinence - New Onset



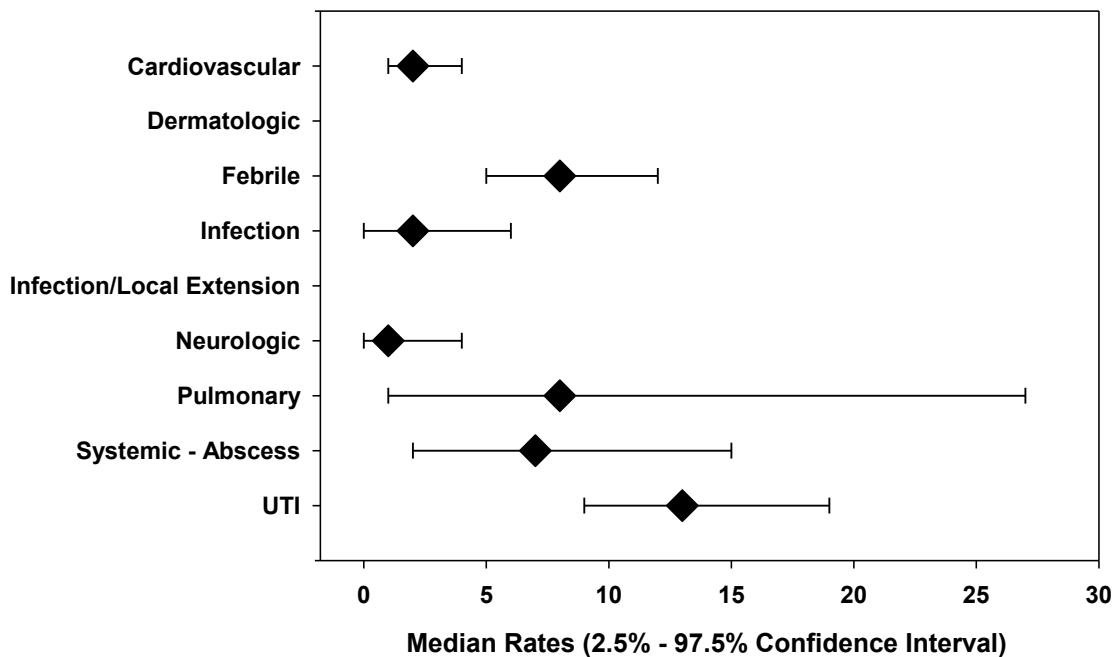


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Urgency Urge Incontinence - Pre-Existing

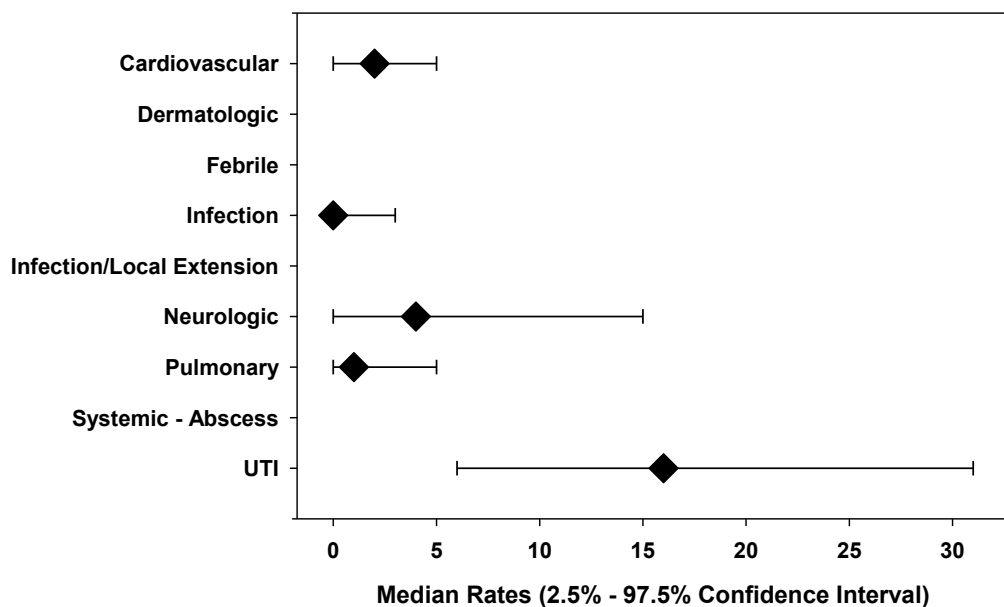


### No Prolapse Patients: General Medical Complications All Retropubic Suspensions

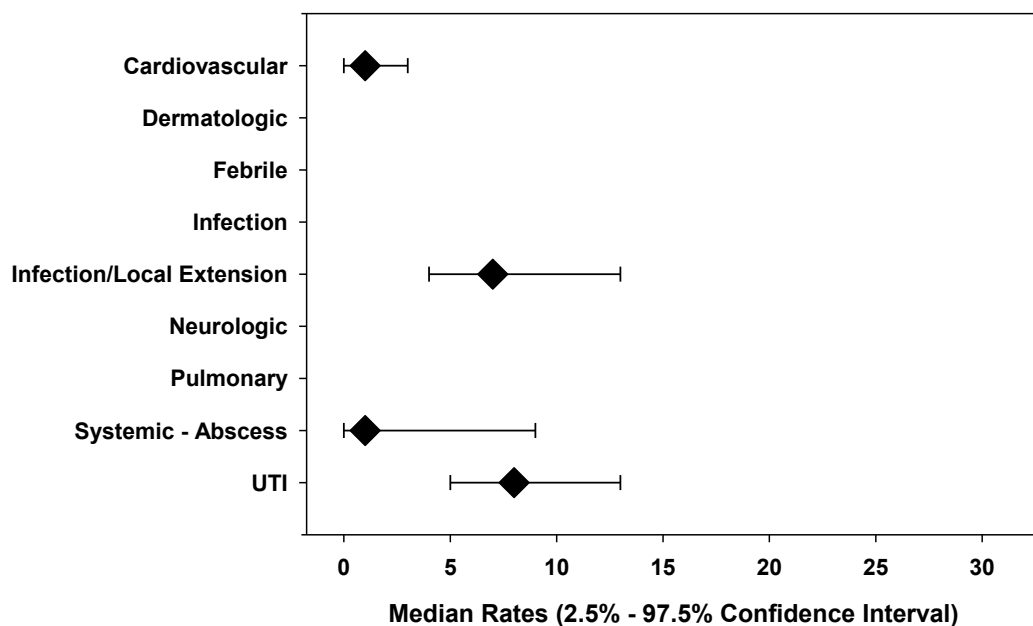


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: General Medical Complications Autologous Fascia Sling

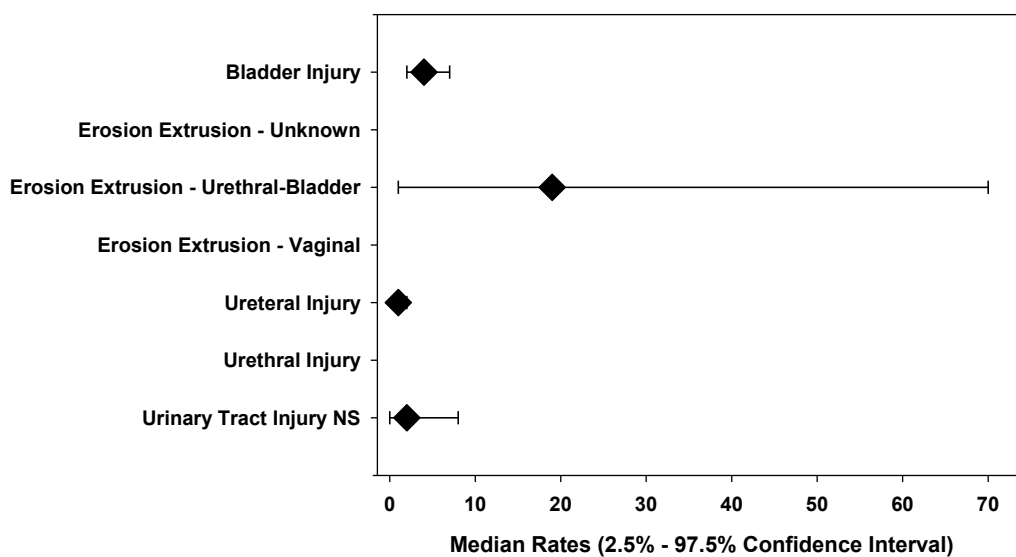


### No Prolapse Patients: General Medical Complications Synthetic at Mid-Urethra

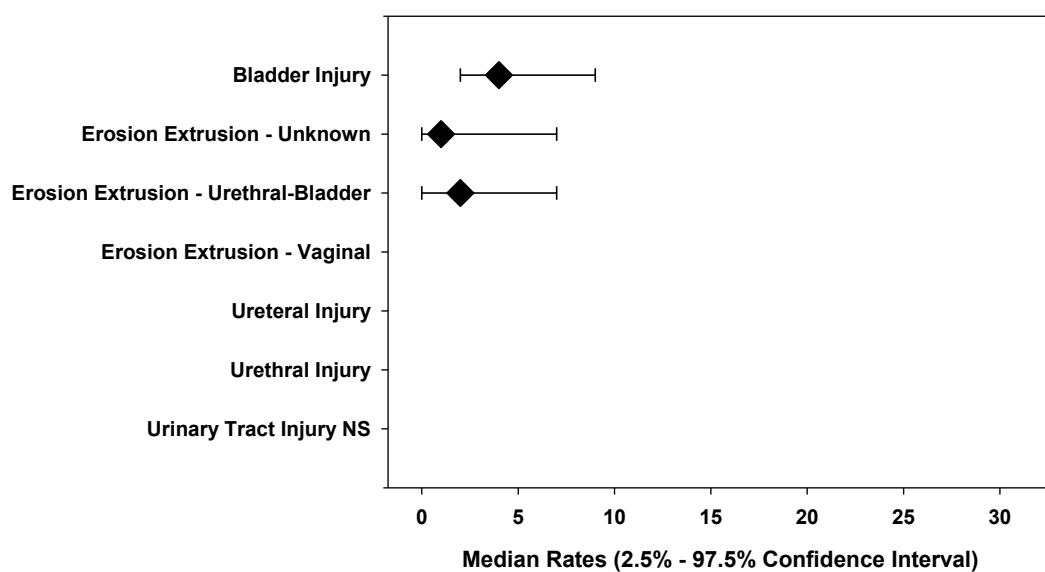


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Operative Complications All Retropubic Suspensions

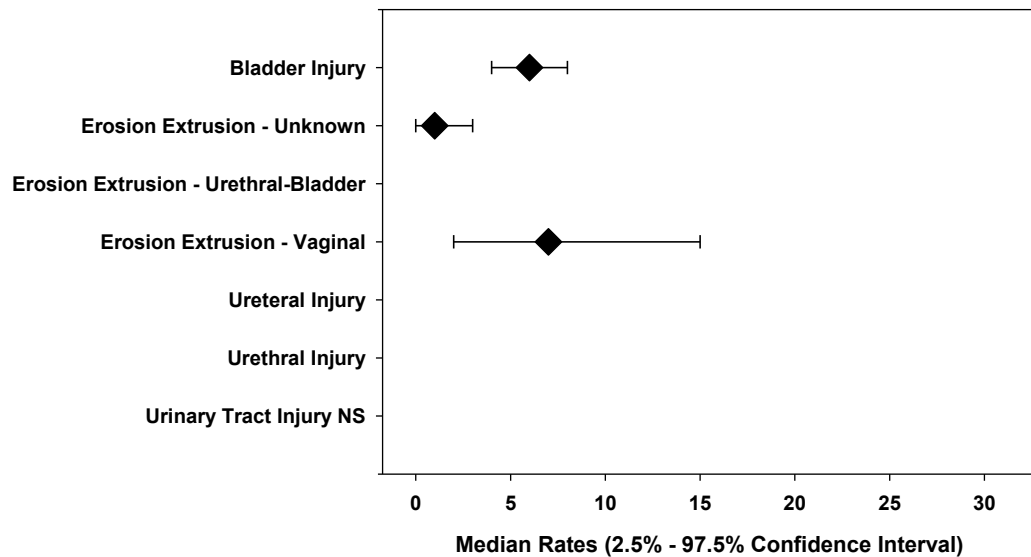


### No Prolapse Patients: Operative Complications Autologous Fascia Sling

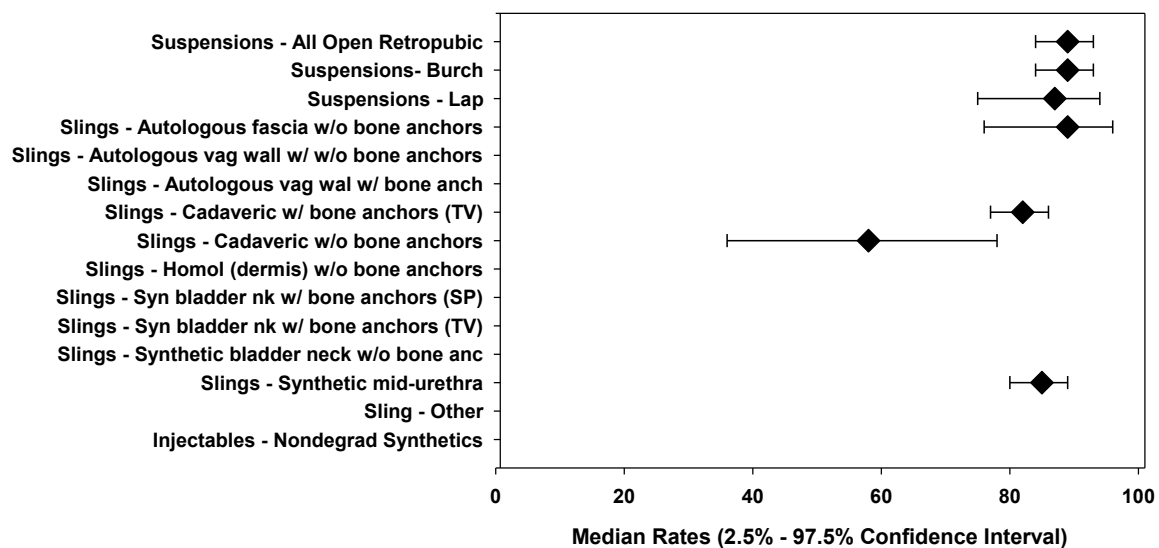


## Appendix A18 – Outcomes Graphs

### No Prolapse Patients: Operative Complications Synthetic at Mid-Urethra

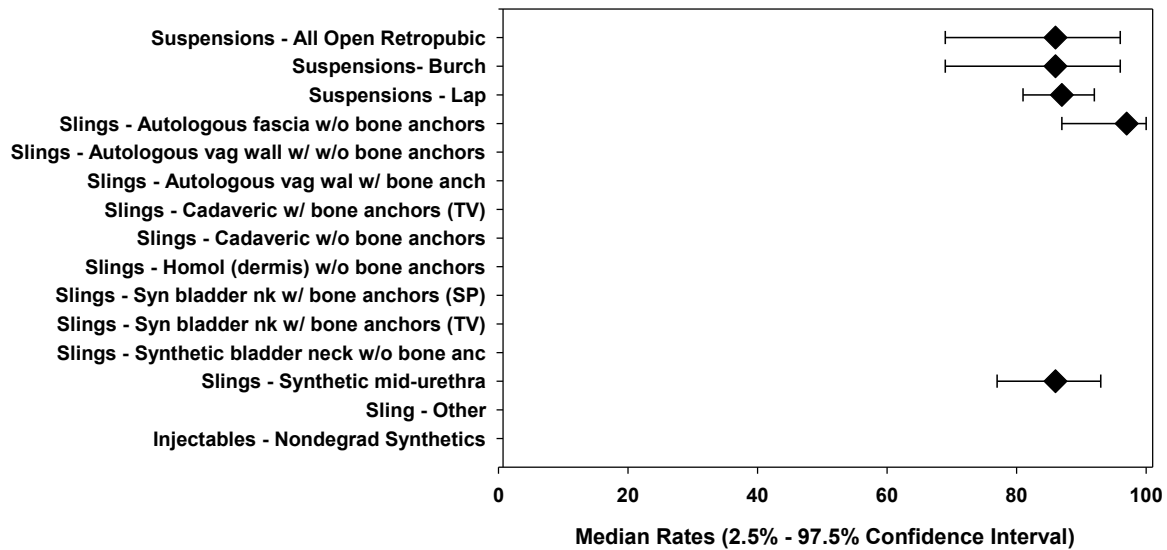


### Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 12-23 Mos

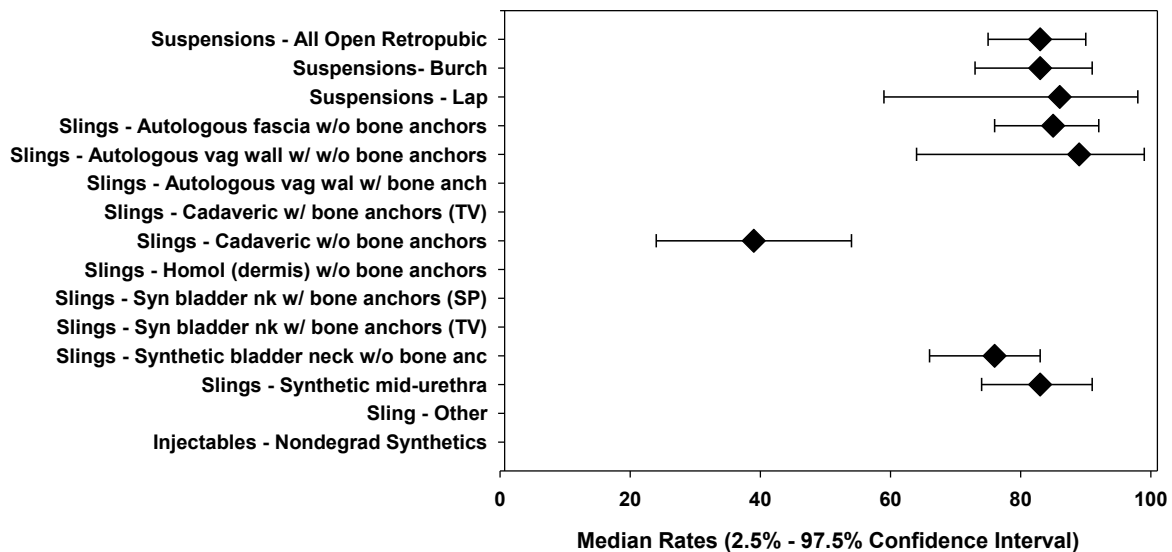


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 12-23 Mos

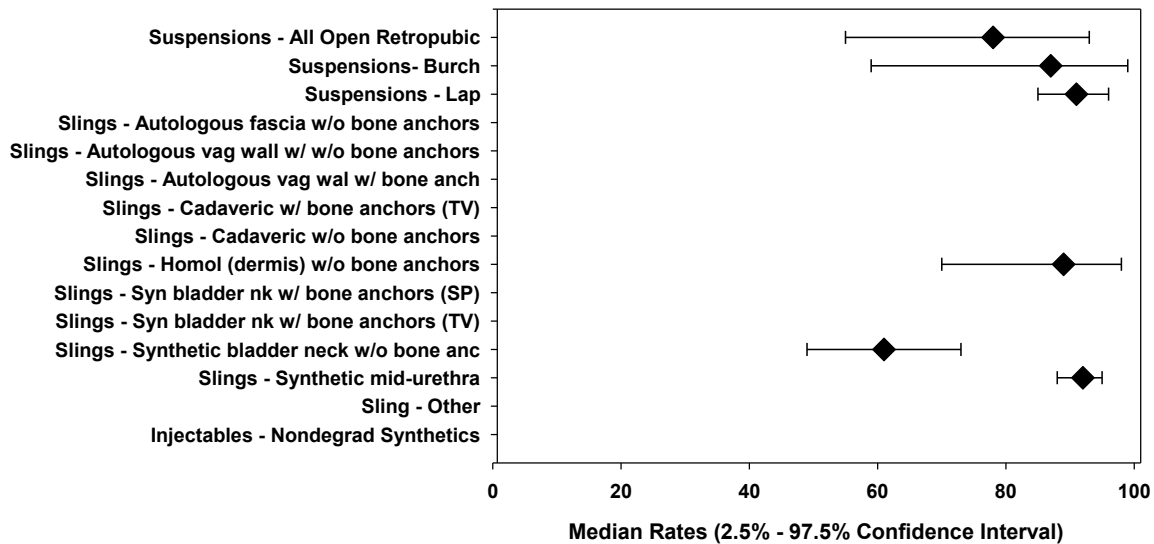


### Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 24-47 Mos

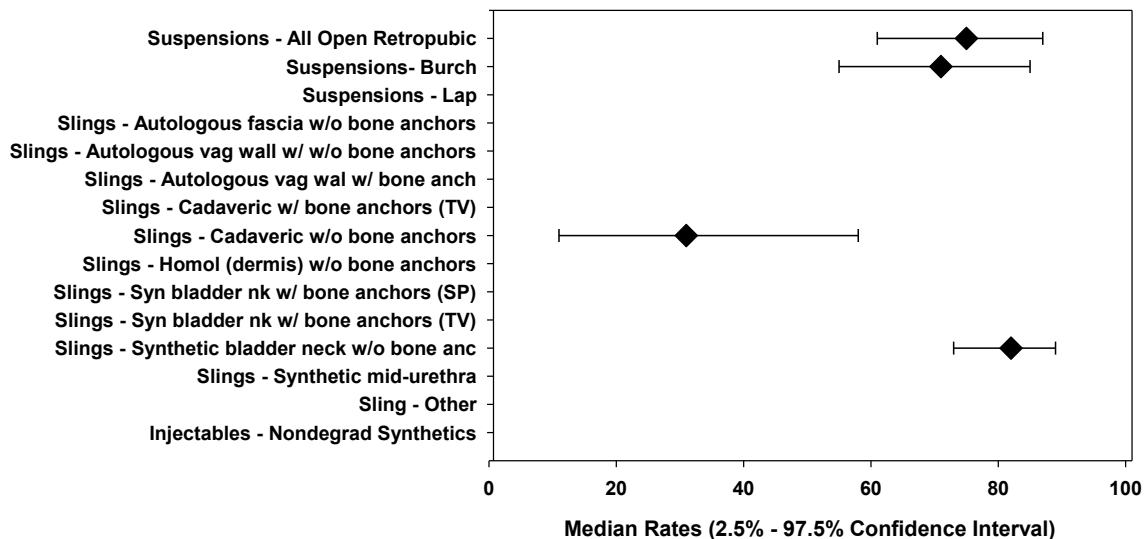


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 24-47 Mos



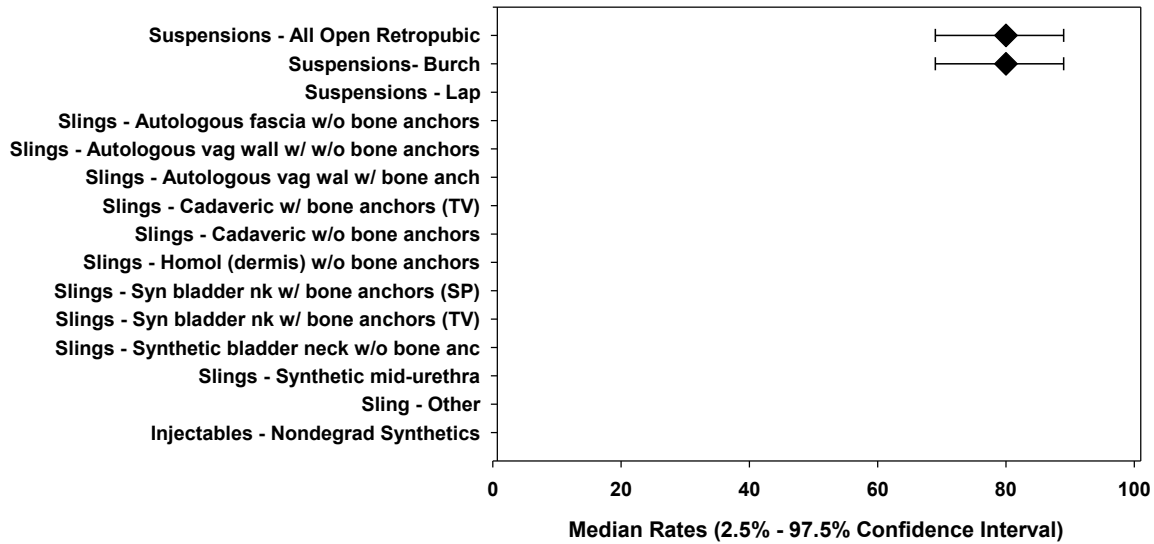
### Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 48+ Mos



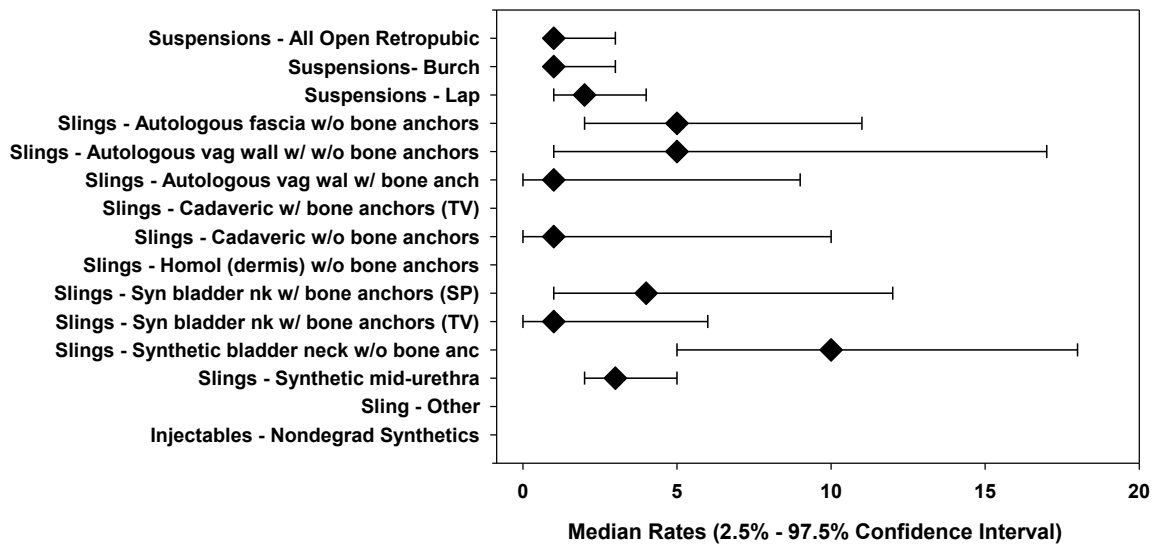


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 48+ Mos

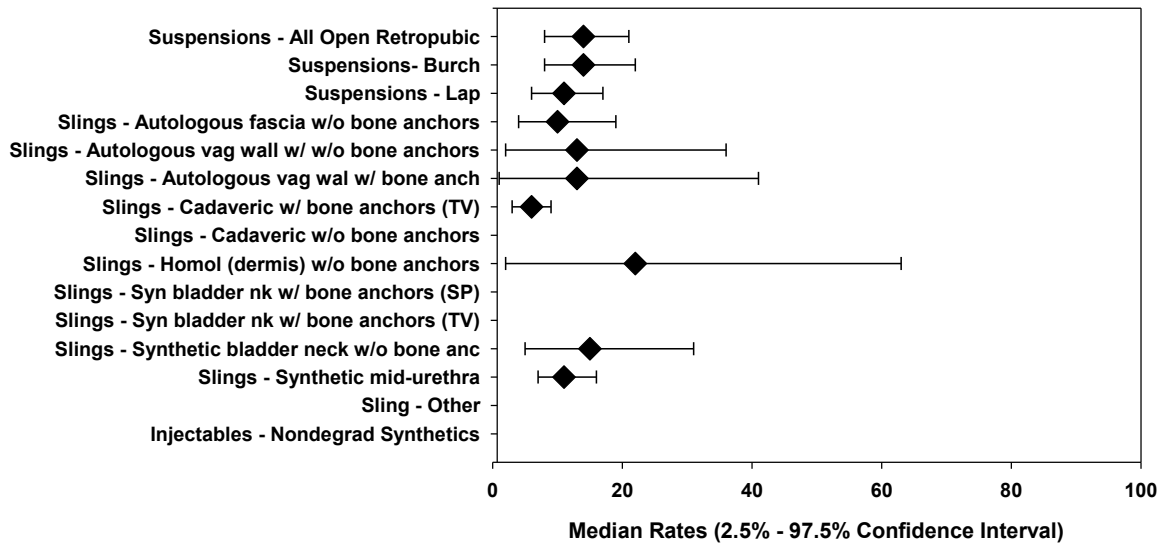


### Any Prolapse Patients: Retention > 28 days or Intervention

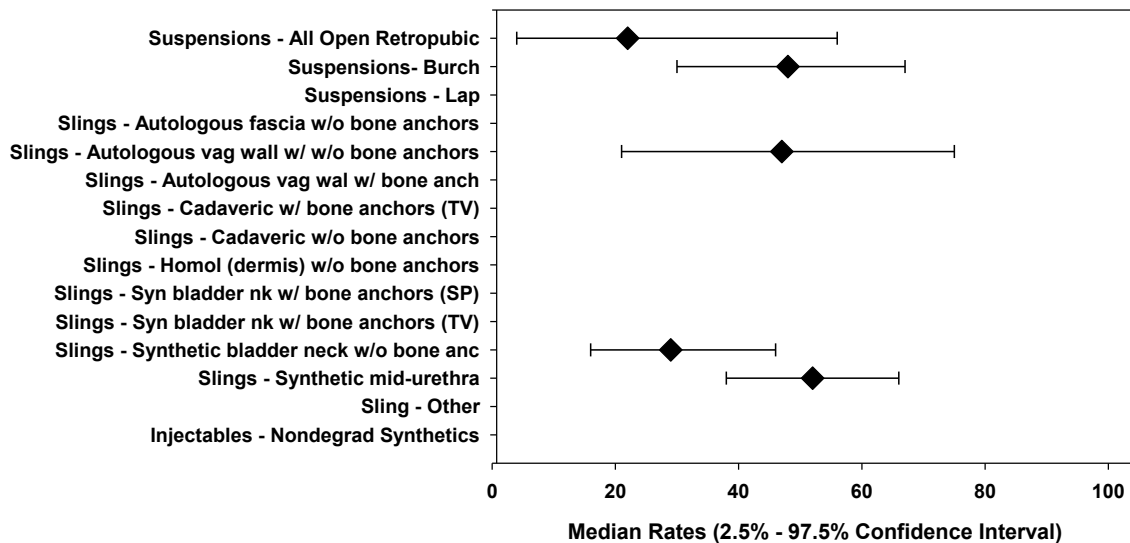


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Urgency Urge Incontinence - New Onset

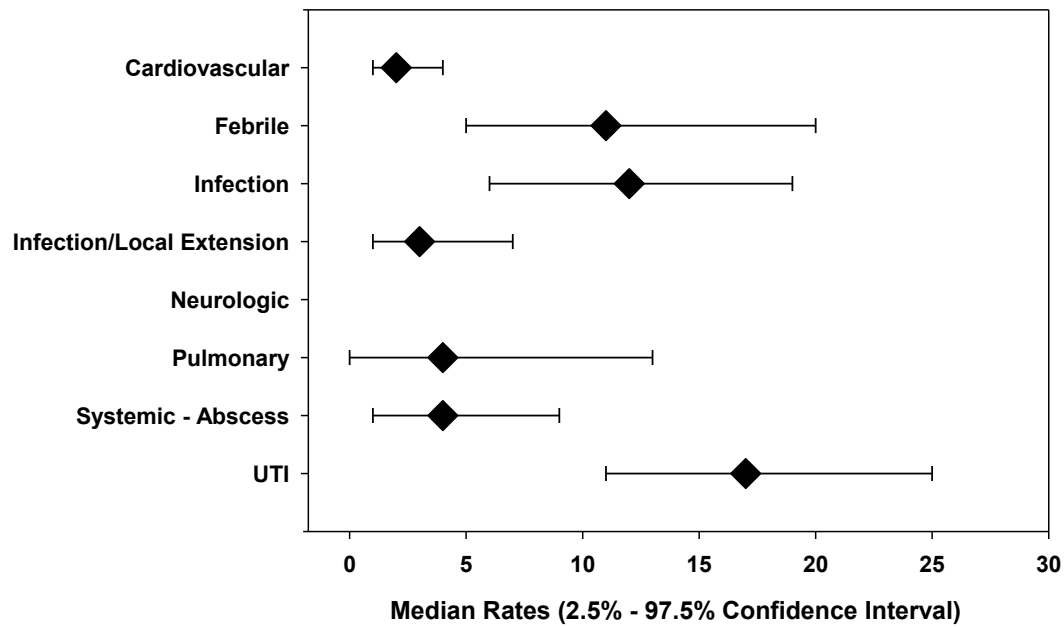


### Any Prolapse Patients: Urgency Urge Incontinence - Pre-Existing

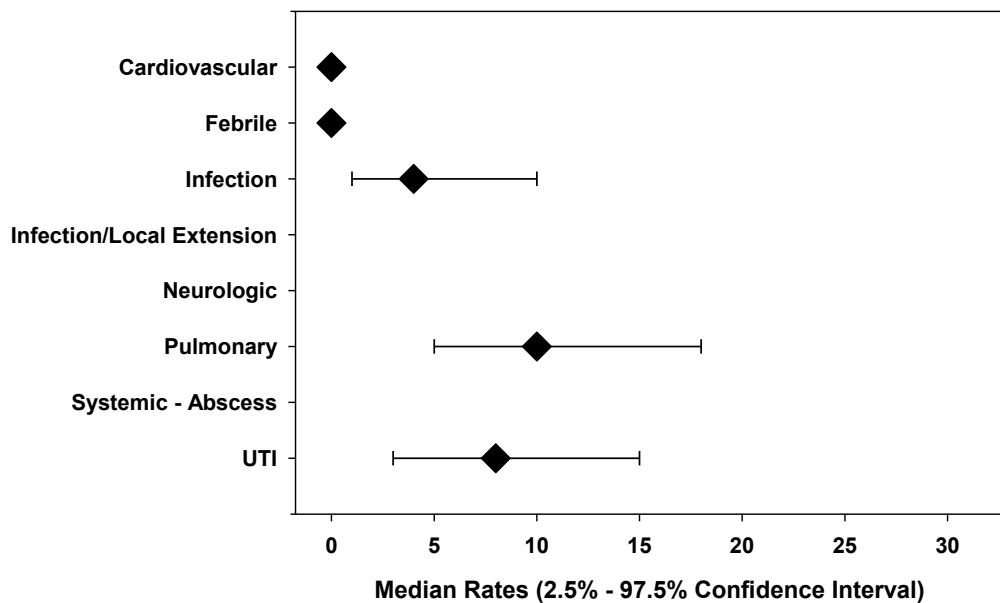


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: General Medical Complications All Retropubic Suspensions

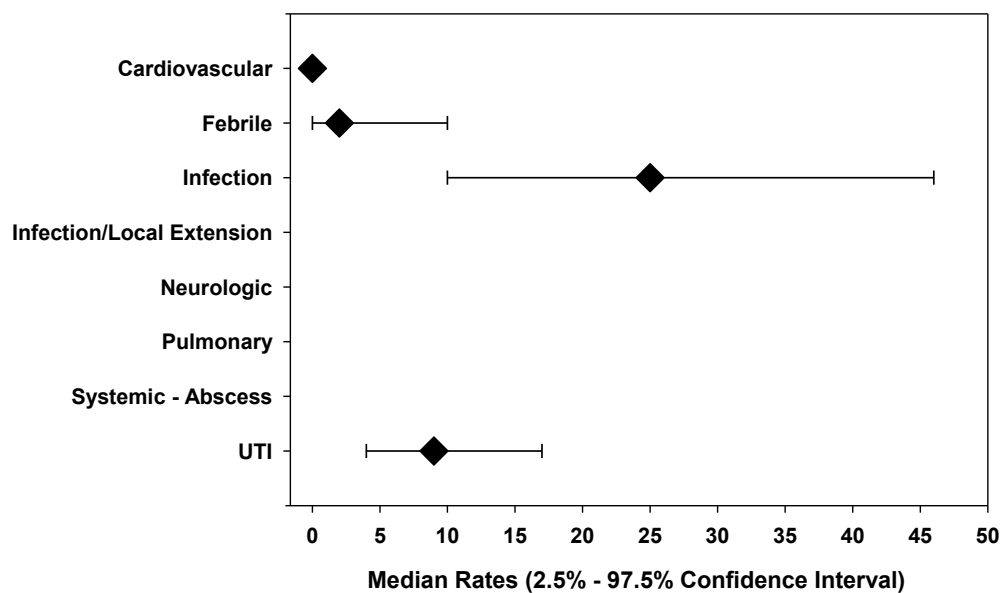


### Any Prolapse Patients: General Medical Complications Autologous Fascia Sling

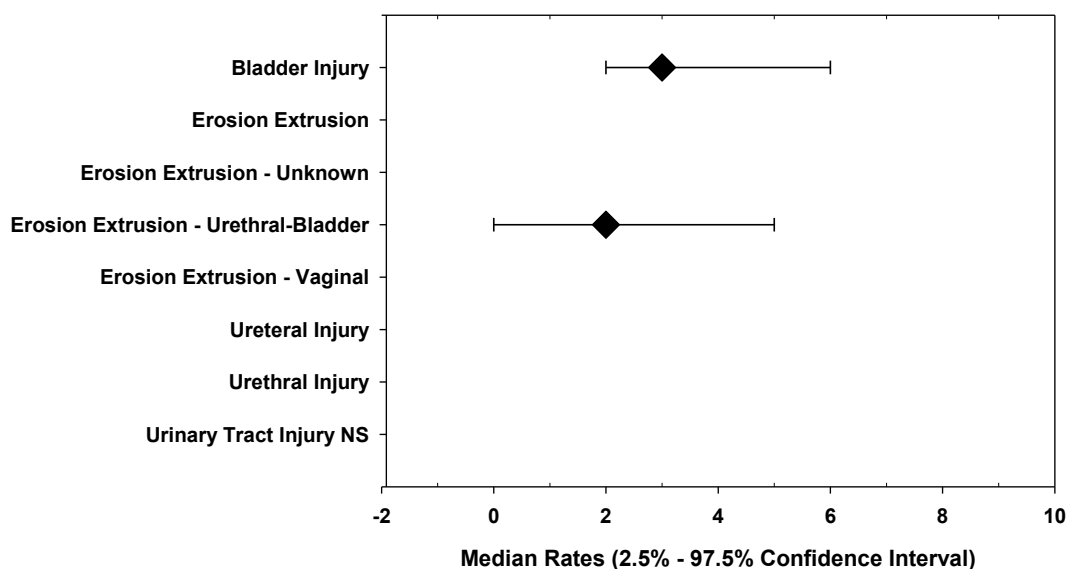


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: General Medical Complications Synthetic at Bladder Neck

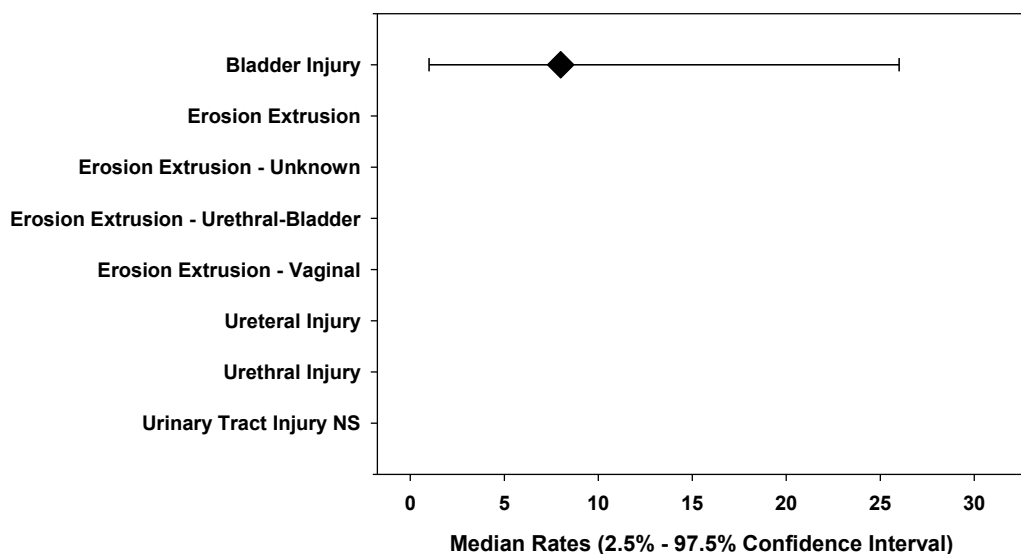


### Any Prolapse Patients: Operative Complications All Retropubic Suspensions

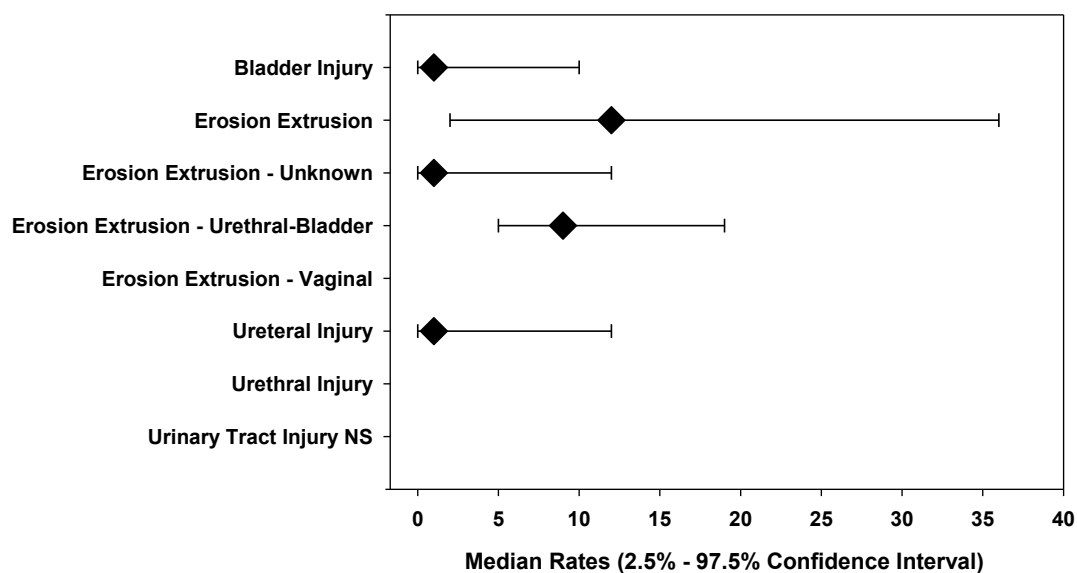


## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Operative Complications Autologous Fascia Sling



### Any Prolapse Patients: Operative Complications Synthetic at Bladder Neck



## Appendix A18 – Outcomes Graphs

### Any Prolapse Patients: Operative Complications Xenograft - Synthetic at Mid-Urethra

